The Pristine™ Long-Term Hemodialysis Catheter: Physicians' Perspectives

Experience-based insights on the placement and benefits of the first and only side-hole free hemodialysis catheter with unique Y-Tip™ distal lumen design.*

With Shaker S. Qaqish, MD; Jeffrey Hoggard, MD, FACP, FASN, FASDIN; and Karn Gupta, MD, FASN, FASDIN

Hemodialysis remains the most common treatment modality for end-stage renal disease. In 2018, approximately 81% of hemodialysis incident patients started their dialysis with a catheter in the United States, and approximately 18% of hemodialysis prevalent patients were using a catheter in December 2018 in the United States.[1] A considerable number of fistulas (28%-53%) fail to mature sufficiently to support dialysis therapy.[2] Failure to mature often commits these patients to a tunneled dialysis catheter (TDC) for a variable length of time until they have a well-functioning arteriovenous access.[2]

When a TDC is necessary, interventional physicians must consider the catheter design and appropriate tip positioning. TDCs are associated with multiple complications, such as central venous stenosis, infection, and thrombosis.[3] Catheter dysfunction as defined by the Kidney Disease Outcomes Quality Initiative (KDOQI) is "failure to attain and maintain an extracorporeal blood flow of 300 mL/min or greater at a prepump arterial pressure more negative than −250 mm Hg."[4]

Select causes of catheter dysfunction are thrombus accumulation/clotting, fibrin sheath formation, mechanical kinking, and positional occlusion.[5] Catheter dysfunction can also result in significant recirculation leading to lower Kt/V. Such a catheter may require exchange, especially when one or both lumens cannot be aspirated.[6]

To learn more about the Pristine™ Catheter, scan this code using your phone's camera.

In a study of two TDC models, the most prominent flow stagnation regions were detected around the side holes and terminal apertures, where the laminar flow from the catheter tip is interrupted by inflow from the side holes.[7] In addition, thrombi have been shown to attach to imperfections in the cut surfaces of side holes.[8,9] Importantly, these clots/thrombi have been characterized as difficult to remove or dissolve in situ.[9]

To avoid complications associated with vessel and right atrial trauma, the latest KDOQI guidelines recommend that the proper location of the TDC tip is at the mid-right atrium. There are different types of right atria, including long tubular, small globular, complex, normal, deep triangular, and mega atrium, but regardless of the type, it is important to place the arterial limb of the catheter tip in a large pool of blood in the right atrium to achieve the prescribed blood flow.[10]

BD's Pristine™ Long-Term Hemodialysis Catheter side-hole free tip is designed to help minimize thrombus adhesion that can be associated with side-hole catheters (Figures 1 and 2). The catheter's innovative Y-shaped, split, symmetrical tip was cast to fit the anatomy of the right atrium with an anterior/posterior (AP) orientation to help optimize flow.

In addition, Pristine™ Catheters have a dual lumen with a double-D–shaped cross-section of the mid-shaft and a short preformed symmetric split-tip devoid of side holes. This helps facilitate blood clot aspiration prior to hemodialysis treatment.

This article highlights experiences of three physicians with the Pristine™ Catheter, allowing them to provide insight on the placement and benefits of this side-hole free hemodialysis catheter with a unique Y-Tip™ distal lumen design.

*As of October 2021, US Market only

What do you believe are the unique features and benefits of Pristine™ Catheter?

Dr. Hoggard: The unique feature is the tip design. The Pristine™ Catheter is designed to support AP tip placement orientation in the mid-right atrium, and this orientation can help to reduce the likelihood of positional occlusion. The Y-Tip™ distal lumen is symmetrical, which is designed to help minimize the amount of recirculation. The tip of Pristine™ Catheter is also side-hole free, which is important as this design can help to minimize thrombus adhesion that can be associated with side-hole catheters and help facilitate blood clot aspiration prior to hemodialysis treatment.

Why did you decide to try placing the Pristine™ Catheter?

Dr. Qaqish: At our practice, we have a large referral volume for catheter malfunction, most of which are due to resistant catheter thrombosis or fibrin sheath formation.

I participated in a feasibility study of the Pristine™ Catheter and found the results worthy of consideration.

Dr. Hoggard: End-stage kidney disease patients have a high morbidity and mortality rate. I think most nephrologists, myself included, are willing to embrace new, promising technologies that offer advancements in design.

The Pristine™ Catheter has a unique Y-Tip™ distal lumen design. From your experience, what are your thoughts on the tunneler and catheter assembly and as well on the insertion of the catheter into the AirGuard™ valved introducer (peel-away sheath)?

Dr. Hoggard: The tunneler, assembly, and insertion are very straightforward and easy. I would highlight that the Pristine™ Catheter Y-Tip™ distal lumen requires a simple pinch together twice during the insertion procedure. First, pinch the Y-Tip™ distal lumen together to slide the tunneler sheath over the compressed tip, and then the tunneling process is no different from any other antegrade hemodialysis catheter. Second, the Y-Tip™ distal lumen simply needs to be pinched together again before inserting through the valved peel-away sheath.

How many Pristine™ Catheters have you placed? How would you describe your experience of placing the Pristine™ Catheter(s)?

Dr. Hoggard: I initially placed Pristine™ Catheters in the Dominican Republic and was impressed with its performance. It was natural for me to begin using this unique catheter when it was cleared by the FDA in the United States this year. I have placed about 20 Pristine™ Catheters and have had no issues with the kits, the placement procedure.

Dr. Qaqish: I have inserted nine Pristine™ Catheters in the United States so far. Standard antegrade TDC placement does not require additional skills.

Dr. Gupta: I have placed about 15 Pristine™ Catheters in the United States. They are quite user-friendly, placed via an antegrade approach, and in general have similar steps to current antegrade catheter insertions. Neither I nor my staff had to learn anything new to place them. The catheter tip tends to auto position itself in the AP orientation as long as you follow the manufacturer's instruction for insertion.

The Pristine™ Catheter is designed to help facilitate accurate tip placement in the mid-right atrium in AP orientation. After placement, were you able to confirm with imaging that the Pristine™ Catheter tip was in AP orientation? Did you have any difficulty?

Dr. Gupta: Yes, the catheter design helps to ensure that the catheter orients into the AP orientation. We were able to confirm the AP orientation via an oblique view. The only difficulty we had was in an obese patient in which lateral view was not as clear, but orientation was indirectly confirmed from AP view.

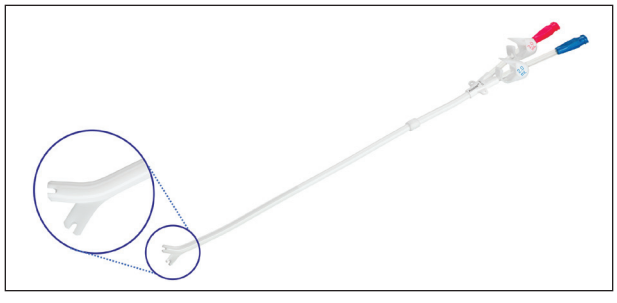

Figure 1. The Pristine™ Catheter with zoomed-in view of the Y-Tip™ distal lumen.

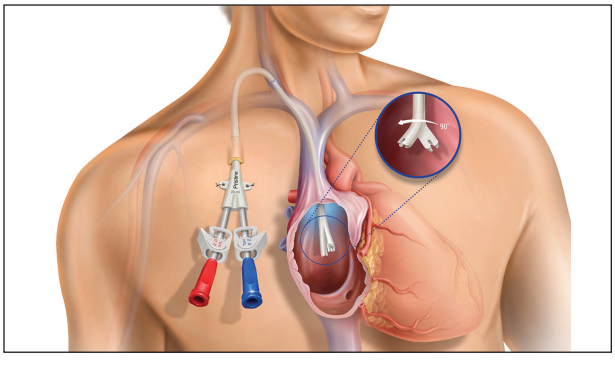

Figure 2. Pristine™ Catheter's unique Y-Tip™ distal lumen to support AP tip placement orientation in the mid-right atrium.

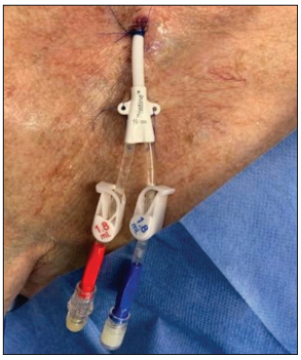

Figure 3. Placing the Pristine™ Catheter with the red luer toward the patient's right side allows the arterial limb to be placed anteriorly in the right atrium.

On which side of the patient did you place the Pristine™ Catheter? Right, left, or both?

Dr. Hoggard: Both right and left internal jugular veins have been used successfully.

If you placed the Pristine™ Catheter on the left side, was the experience of placing the Pristine™ Catheter similar to the placement of other hemodialysis catheters? Were there any challenges specific to the Pristine™ Catheter?

Dr. Gupta: Yes, the experience was no different whether placing the catheter from the right or left side. As with all left-sided catheter placements, one needs to be careful while navigating the tortuous anatomy of central veins.

After placing hemodialysis catheters, do you perform an aspiration test to confirm patency? If so, why do you think this step is important?

Dr. Qaqish: Yes, I perform an aspiration test with a 20-mL syringe to each port, which can help to avoid early catheter dysfunction. If I encounter any resistance during my aspiration test, most of the time it is correctable by adjusting the catheter tip position properly in the right atrium.

Do you have any suggestions or recommendations for physicians who place a Pristine™ Catheter for the first time?

Dr. Qaqish: To achieve the desired successful outcomes of this distinctive catheter, proper placement and orientation are key.

A. The red luer toward the lateral side of the patient (Figure 3)

B. The tip properly positioned in the right atrium

C. Perform the aspiration test and troubleshoot until no resistance is encountered. ■

1. United States Renal Data System. 2020 annual data report. Accessed October 20, 2021. https://adr.usrds.org/2020/
2. Asif A, Roy-Chaudhury P, Beathard GA. Early arteriovenous fistula failure: a logical proposal for when and how to intervene. Clin J Am Soc Nephrol. 2006;1:332-339. doi: 10.2215/CJN.00850805
3. Agarwal AK, Patel BM, Haddad NJ. Central vein stenosis: a nephrologist's perspective. Semin Dial. 2007;20:53-62. doi: 10.1111/j.1525-139X.2007.00242.x
4. National Kidney Foundation. Guideline 7. Prevention and treatment of catheter and port complications. KDOQI clinical practice guidelines and clinical practice recommendations for 2006 updates: hemodialysis adequacy, peritoneal dialysis adequacy and vascular access. Am J Kidney Dis. 2006; 48:S1-S322. doi: 10.1053/j.ajkd.2006.04.040
5. Chan MR. Hemodialysis central venosu catheter dysfunction. Semin Dial. 2008;21:516-521. doi: 10.1111/j.1525-139X.2008.00495.x
6. Ponikvar R, Buturović-Ponikvar J. Temporary hemodialysis catheters as a long-term vascular access in chronic hemodialysis patients. Ther Apher Dial. 2005;9:250-253. doi: 10.1111/j.1774-9987.2005.00265.x
7. Clark TW, Isu G, Gallo D, et al. Comparison of symmetric hemodialysis catheters using computational fluid dynamics. J Vasc Interv Radiol. 2015;26:252-259 e2. doi: 10.1016/j.jvir.2014.11.004
8. Ash SR. Advances in tunneled central venous catheters for dialysis: design and performance. Semin Dial. 2008;21:504-515. doi: 10.1111/j.1525-139X.2008.00494.x
9. Moore HL. Side holes at the tip of chronic hemodialysis catheters are harmful. J Vasc Access. 2001;2:8-16. doi: 10.1177/112972980100200103
10. Ross JR, Gallichio M, Davidson I. Dialysis catheter placement and selection based on the right atrium. Endovasc Today. 2015;14:52-54.

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Pristine™ Long-Term Hemodialysis Catheter

Indications: The Pristine™ Long-Term Hemodialysis Catheters are indicated for use in attaining short-term or long-term vascular access for hemodialysis, apheresis, and infusion. Access is attained via the internal jugular vein, subclavian vein, or femoral vein. Catheters longer than 40 cm are intended for femoral vein insertion. Catheters may be inserted percutaneously.

Contraindications: · Thrombosed vessels · Confirmed infection, bacteremia or septicemia · Inadequate anatomy for placement of the device · Known or suspected sensitivity to the device materials · Prior or unresolved venous thrombosis at the proposed placement site.

Warnings and Precautions: · The catheter should be inserted and removed only by a qualified, licensed physician or other healthcare professional authorized by and under the direction of such physician. · The medical techniques and procedures described in these instructions do not represent ALL medically acceptable protocols, nor are they intended as a substitute for the physician's experience and judgment in treating any specific patient. · The content of this pack is supplied EO (Ethylene Oxide) STERILE, non-pyrogenic. · Use aseptic technique during catheter insertion, use, maintenance and removal. · Do not use the device if the "Use-By" date indicated on the package label has passed. Do not use the catheter if package has been previously opened or damaged. Inspect the device package and content to verify that no damage has occurred as a result of shipping, handling and/or storage. If damage to the sterile barrier or the device is noted, do not use the device. Retain the package with the contents and notify your BD representative. · Single patient use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure, which may result in patient injury, illness or death. Reuse, reprocessing or re-sterilization may create a risk of contamination to the device and/or may cause patient infection or cross-infection, including, but not limited to the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. · Keep the catheter extension tubing clamped at all times when not in use and fill the catheter with sterile saline prior to implantation to avoid air embolism. With each tubing change, purge air from the tubing and aspirate any air from the catheter. · If the catheter is intended to be placed in a internal jugular or subclavian vein, it is recommended to place the patient on a cardiac monitor during the procedure for detection of arrhythmia. · To avoid vessel perforation and damage, do not forcibly insert the guidewire, dilators, or valved pull-apart sheath/introducer. · Do not insert the valved pull-apart sheath/introducer further than necessary: depending upon patient size and access site, it may not be necessary to insert the entire length of the introducer into the vessel. · The valved pull-apart sheath/introducer is not a hemostasis valve. It is designed to reduce blood loss and the risk of air intake. · The valved pull-apart sheath/introducer is not intended to create a complete two-way seal nor is it intended for arterial use. · When using a "J" end guidewire straighten the end allowing introduction into the introducer needle. Do not insert or withdraw the guidewire forcibly from any component: the wire could break or unravel. · After placement of the catheter check for catheter tip location by imaging. · Do not nick the catheter when suturing. · Do not excessively tighten the suture when tying at the venotomy site. · Prolonged exposure to ultraviolet light can damage the catheter. · Acetone and Polyethylene Glycol (PEG)-containing ointments should not be used with polyurethane catheters. · Alcohol disinfectants (or alcohol containing antiseptics, such as chlorhexidine) may be used to clean the catheter; however, care should be taken to avoid prolonged or excessive contact with the solution. · The following antiseptics, chlorhexidine gluconate 4% (Hibiclens™), sodium hypochlorite (ExSept Plus™), povidone iodine (Povidone ointment, Betadine™ solution) and hydrogen peroxide can be used on the catheter and at the exit site; however, care should be taken to avoid prolonged or excessive contact with the solution. Solution should be allowed to completely dry before applying a dressing. Intermixing of these solutions has not been tested and is not recommended. · The following antibiotics, mupirocin 2% ointment, Polyspoirn™ ointment and gentamicin can be used on the catheter and at the exit site. · Avoid excessive tightening of catheter's connections when connecting bloodlines, caps or syringes. Overtightening might crack the connections. · Do not clamp the dual lumen portion of the catheter; clamp only the extensions. Use only smooth-jawed forceps for clamping when not using the clamp supplied with the catheter. · Clamping the catheter repeatedly in the same spot could weaken the tubing: change the position of the clamp regularly to prolong the life of the tubing. Avoid clamping near the adapter and hub. · Exercise caution when using sharp instruments near the catheter. Catheter tubing can tear when subjected to nicks, excessive force, or rough edges. · Inspect the catheter frequently for nicks, scrapes, cuts, etc. which could impair its performance. · 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. · Remove the catheter as soon as it is no longer necessary. · Catheter removal should be performed by adequately trained healthcare professional or delegate. During catheter removal, do not cut the catheter prior to removal from the vein to prevent the occurrence of an air embolism. If there is resistance as the catheter is being withdrawn from the vein, avoid aggressive pulling to reduce the resistance. · Free the cuff and surfaces from the tissue prior to removal. When removing the catheter, DO NOT use a sharp, jerking motion or undue force; this may tear the catheter. · After use, dispose of the product and its packaging in accordance with administrative and/or local, state and federal laws and regulations. · Never use after expiry date. · To avoid damage to the vessels and viscus, infusion pressure must not exceed 25psi (172 kPa); the use of a 10 mL or larger syringe is recommended because smaller syringes generate more pressure than larger syringes. Subclavian access should only be used when no other upper-extremity or chest-wall options are available. · To prevent air embolism, keep the catheter clamped at all times when not attached to a syringe, IV tubing, or bloodlines. · Cannulation of the left internal jugular vein was reportedly associated with a higher incidence of complications compared to catheter placement in the right internal jugular vein. · As reported in literature, left sided catheter placement may provide unique challenges due to the right angles formed by the innominate vein and at the left brachiocephalic junction with the SVC. · If arterial blood is aspirated, remove the needle and apply immediate pressure to the site for at least 15 minutes. Ensure that the bleeding has stopped and that no hematoma has developed before attempting to cannulate the vein again. · Do not pull back standard guidewire over needle bevel as this could sever the end of the guidewire. The introducer needle must be removed first. · If the microintroducer 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. · Place a thumb over the orifice of the sheath to minimize blood loss and risk of air aspiration. · The risk of infection is increased with femoral vein insertion. Avoid exit site at groin area. · DO NOT pull tunneler out of the primary incision at an angle. Keep tunneler straight to prevent damage to the catheter tip. The catheter can be bent slightly. · Care should be taken NOT to force the dilator sheath introducer assembly into the vessel during insertion as vessel damage including perforation could result. As reported in literature, left sided catheter placement may provide unique challenges due to the right angles formed by the innominate vein and at the left brachiocephalic junction with the SVC. · Cardiac arrhythmias may result if the guidewire is allowed to touch the walls of the right atrium. · Care should be taken not to advance the split sheath too far into vessel as a potential kink would create an impasse to the catheter. · To prevent air embolism and/or blood loss, place thumb over the exposed orifice of the sheath introducer. · Ensure that the introducer sheath is only torn externally. Catheter may need to be further pushed into the vessel as sheath is torn. · For optimal product performance, do not insert any portion of the cuff into the vein. · Do not allow the catheter to move out of the vein with the sheath. Ensure that the vein is not bleeding around the catheter. · To avoid damage to vessels and viscus, infusion pressures should 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. · Do not suture through any part of the catheter. · Acetone and 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. · Before flushing, pull the plunger back to verify blood flow and to ensure that there are no blood clots. Do not flush clots through the catheter (see Thrombi Formation). · Never forcibly flush an obstructed lumen. · Thrombolytic agents may cause systemic fibrinolysis if infused into circulation. Refer to the manufacturer's instructions, indications for use and contraindications before using Thrombolytic agents. Stereptokinase is not recommended, it has been reported to be anaphylactogenic. · Keep the catheter clamped at all times except for when connected to the bloodlines or syringe during treatment. · 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 BD hemodialysis catheter Luer-lock connectors.

Potential Complications: · Air embolism · Arterial puncture · Brachial plexus injury · Cardiac arrhythmia · Cardiac tamponade · Catheter erosion or extrusion through the skin · Catheter occlusion or breakage · Catheter thrombosis · Catheter tip migration or malposition · Deep vein thrombosis - lower extremity · Endocarditis · Exit site infection · Exsanguination · Extravasation · Femoral artery bleed · Femoral artery damage · Femoral artery dissection · Femoral nerve damage · Femoral vein occlusion · Fibrin sheath formation · Hematoma · Hemorrhage · Hemothorax · Hydrothorax · Inferior vena cava injury · Intolerance reaction to implanted device · Lower extremity ischemia · Mediastinal widening · Pneumothorax · Pulmonary emboli · Pulmonary embolism · Retroperitoneal bleed · Right arterial puncture · Sepsis · Subclavian artery puncture · Subclavian vein stenosis · Subcutaneous tunnel infection · Superior vena cava puncture · Thoracic duct injury · Thoracic duct laceration · Thrombosis of vein · Trauma to major vessel or right atrium · Tunnel infection · Venous stenosis

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