

Introducing Chameleon™: The Next Generation of PTA Balloons

PTA and injection. Combined.



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The prevalence of end-stage renal disease (ESRD) is well documented. In the United States alone, there are over 600,000 patients undergoing hemodialysis, and globally, over 2 million patients rely on hemodialysis. Hemodialysis access site maintenance is therefore critical, with access site failure being the most important factor regarding morbidity in these patients. Reduced flow or no flow issues in fistulas and grafts lead to significant hospitalization rates in 20% of ESRD patients, with a cost to the United States health care system of over \$1 billion annually.¹ Endovascular procedures, including the use of percutaneous transluminal angioplasty (PTA) balloons, are well established as successful techniques for treating dialysis access stenoses, resulting in prolonged patency of the access.

THE CHAMELEON™ BALLOON DESIGN

The Chameleon™ balloon dilatation catheter (AV Medical Technologies Inc.), with proprietary Supervision™ design, functions as a high-pressure angioplasty balloon with the injection capability of a diagnostic catheter. It is indicated for PTA of the femoral, iliac, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous (AV) dialysis fistulas. Chameleon™ is also indicated for the infusion of diagnostic or therapeutic fluids.

The Chameleon™ balloon catheter's unique Supervision™ design incorporates a third port on the

hub of the catheter (Figure 1, injection port). This luer lock injection port allows for connecting of commonly used syringes containing the operator's choice of diagnostic (contrast media) or therapeutic fluids. The fluid travels the length of the Chameleon™ catheter and exits through a side port just proximal to the balloon itself. The 0.035-inch over-the-wire platform allows for the injection of fluids, whether the balloon is inflated or deflated, while maintaining guidewire position.

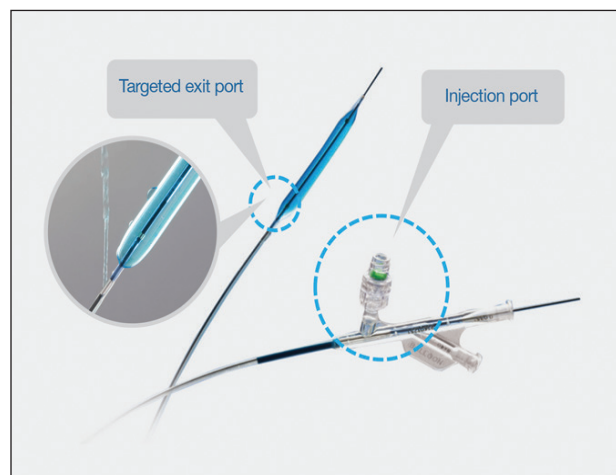


Figure 1. Chameleon™ allows physicians to inject diagnostic or therapeutic fluids through the catheter at any time during the procedure, whether the balloon is inflated or deflated, all while maintaining wire position.

CHAMELEON™ BALLOON DILATATION CATHETER

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The Chameleon™ has been cleared by the US Food and Drug Administration and has European CE Mark approval. It is currently in a limited market release at a select number of sites in the United States.

Would you please share your initial observations regarding the Chameleon™ balloon catheter?

Dr. Kaufman: The first time that I saw it, I thought, “Why didn’t I think of that?” This device addresses several needs associated with dialysis interventions and is intuitive to use. The proximal injection port on the catheter permits more distance between the operator and the patient during injections (reducing radiation exposure) and eliminates the need to compress outflow for reflux imaging (reducing repeated injections as well as exposure). Furthermore, the wire stays in place for the entire procedure, and the integrated balloon is high pressure.

Dr. Hoggard: There really is no learning curve with the Chameleon™ device. It performs like any other high-pressure PTA balloon, and using the side port is very intuitive. You simply attach a luer lock syringe to the injection port and deliver fluids the same way you would through a diagnostic catheter.

How is the image quality when injecting through the Chameleon™ side port?

Dr. Ross: Image quality was one of the first aspects of the Chameleon™ system that we reviewed at our location. We wanted to know if we could image at least as well through Chameleon™ as through a standard 5-F endhole catheter. We now have used a large quantity of these devices in a variety of cases. The image quality is very good and similar to imaging through a standard diagnostic catheter. There are no extra moving parts or special steps to the procedure. In fact, we are able to eliminate a number of steps when using Chameleon™.

Dr. Hoggard: I’ve also used the Chameleon™ balloon in a wide variety of cases. It’s great to be able to deliver contrast whether the balloon is inflated or deflated and obtain high-quality images. I especially like the security of maintaining wire access throughout cases. We’ve all had cases where we have pulled the wire and then struggle to regain wire position. Chameleon™ eliminates this potential complication and enables an efficient procedure.

Can you provide some examples of when Chameleon™ has been helpful in your practice?

Dr. Hoggard: Chameleon™ is terrific for treating juxta-anastomotic lesions (Figure 2). In these cases, we obtain retrograde access, working toward the anastomosis. The guidewire is advanced across the anastomosis to the arterial side, and the balloon is advanced and inflated. With standard balloons, we then have to do a series of

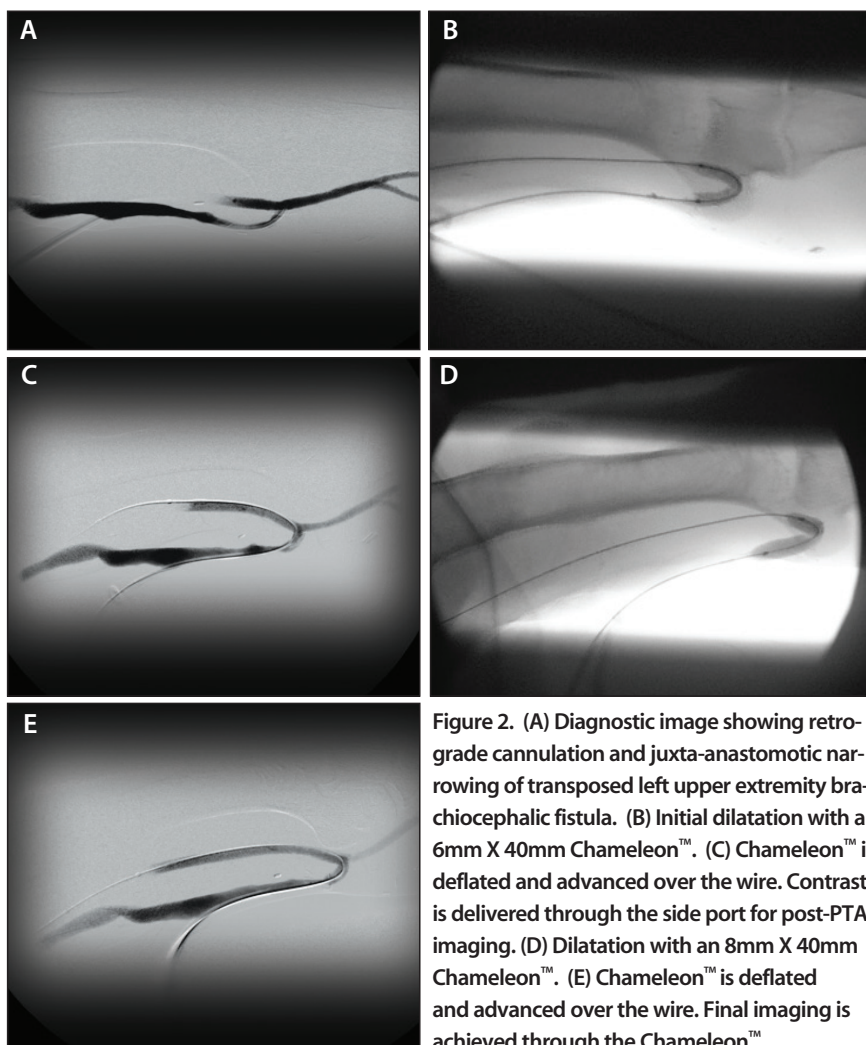


Figure 2. (A) Diagnostic image showing retrograde cannulation and juxta-anastomotic narrowing of transposed left upper extremity brachiocephalic fistula. (B) Initial dilatation with a 6mm X 40mm Chameleon™. (C) Chameleon™ is deflated and advanced over the wire. Contrast is delivered through the side port for post-PTA imaging. (D) Dilatation with an 8mm X 40mm Chameleon™. (E) Chameleon™ is deflated and advanced over the wire. Final imaging is achieved through the Chameleon™.

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device exchanges to obtain images, perform additional inflations, and reassess the results. With Chameleon™, we simply deflate the balloon, advance the catheter, and inject contrast through the side port. Whether the case involves one or multiple inflations, we are saving time by eliminating device exchanges. Another application is declotting of AV grafts. We're typically working in the dark on these cases because there is no flow. Chameleon™ allows us to visualize and dilate with one device, shortening the procedure time by eliminating exchanges.

Dr. Ross: With Chameleon™, we get real-time feedback by delivering contrast during or right after balloon inflation. We immediately know where we stand. We can work with the flow, against the flow, and inject while the balloon is inflated or deflated—this is really helpful in just about every type of dialysis access case that we see.

Dr. Kaufman: As I previously mentioned, reflux imaging is very easy with this device (Figure 3). With the balloon inflated, injection through the side port demonstrates the arterial anastomosis, with ample distance between the operator and patient to position a radiation shield.

Dr. Hoggard: I appreciate the ability to deliver a small amount of contrast directly to the area of stenosis. For patients with maturing fistulas, who are not yet on dialysis, reducing contrast volume is critical to preserving renal function. I recently had a case with a female patient in her mid-50s. She wasn't on hemo-

dialysis yet and recently had a fistula created in her left arm. The initial angiogram revealed a flow-limiting outflow stenosis. I advanced a 7mm X 40mm Chameleon™ and dilated the lesion. After deflating the balloon, I injected a very small amount of contrast to perform the final imaging. The proximity of the exit port was a real benefit here. I avoided device exchanges and eliminated the use of a diagnostic catheter. Most importantly, I achieved a quality image with dramatically less contrast than if I had injected through the sheath.

What do you see for the future of Chameleon™? Are there other applications in which you would like to use it?

Dr. Hoggard: I'm excited to use the larger-diameter balloons that recently received regulatory clearance in the United States. As we work in the cephalic arch and more centrally, it will be great to have precise contrast delivery, which will result in using lower amounts of contrast.

Dr. Kaufman: The side port and high-pressure balloon can be creatively used in a number of situations. During dialysis access procedures, the side port allows delivery of medication, anticoagulants, and lytics. I've used the device (off label) during angioplasty of chronic venous thrombosis and can envision nonvascular uses as well, such as cholangioplasty.

Dr. Ross: I appreciate the efficiency that Chameleon™ provides in dialysis access cases. It makes the difficult cases simple and the simple cases even simpler. It offers advantages for experienced operators as well as those training in dialysis access procedures. ■

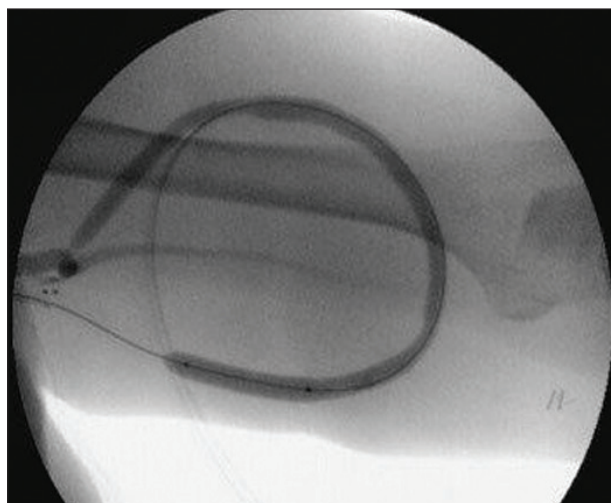


Figure 3. Chameleon™ is inflated to occlude outflow and contrast is delivered through the side port.

1. Roy-Chaudhury P, Kelly BS, Melham M, et al. Vascular access in hemodialysis: issues, management, and emerging concepts. *Cardiol Clin.* 2005;23:249-273.

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