

Innovative AV access technique study

A novel thrombectomy technique using the Chameleon™ PTA balloon catheter to perform imaging, thrombectomy and angioplasty

10/10

Technical success rate[†]

AVF cases (n=4)

AVG cases (n=6)

[†]In a retrospective, single-center case study

Perform contrast and medication injection (e.g. lytics) through the injection lumen — making an introducer sheath optional.

Procedural time outcomes

Thrombectomy of a clotted AVF or AVG performed with a single device

21 minutes

Average procedural time¹

4.5 minutes

Average fluoroscopy time¹

37mL

Average contrast volume¹

Cost savings¹

- Eliminate the need for introducer sheaths
- Comparative cost differences using PTA balloon(s) vs. mechanical thrombectomy

A procedure that matters¹

Thrombectomy is critical for prolonged AV access life and is a significant source of health care expenditures in patients with ESRD.

~ 470,000

ESRD patients on hemodialysis in the US²

65%-85%

Vascular access loss due to Thrombosis¹

0.5-2.0

AVG Thrombosis episodes (per graft / year)¹

66.05 min

Standard thrombectomy procedural time (average)¹



Important safety information

Please see Full Prescribing Information in the IFU.

Indications for use

The Chameleon™ PTA Catheter is indicated for use in Percutaneous Transluminal Angioplasty of the femoral, iliac, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The Chameleon enables the infusion of diagnostic or therapeutic fluids. This catheter is not for use in coronary arteries or cerebral vasculature.

Contraindications

DO NOT use the Chameleon™ Device:

- For coronary arteries nor for the delivery and/or expansion of stents.
- In patients who cannot tolerate anticoagulation therapy.

Warnings

- Single patient use only. Do not re-use, re-process or re-sterilize.
- Use the recommended balloon inflation medium. DO NOT use air or any other gaseous medium (e.g. CO₂) to inflate the balloon or for infusion through the catheter.
- When the catheter is exposed to the vascular system, it should be manipulated only while under high-quality fluoroscopic observation.
- DO NOT manipulate the catheter unless the balloon is fully deflated. Never advance / withdraw against any resistance. DO NOT use excessive force. If resistance is felt, determine the cause and take any necessary remedial action. Applying excessive force to the catheter may lead to tissue trauma and / or device damage.
- DO NOT exceed the RBP recommended on the product label. Balloon rupture may occur if the RBP rating is exceeded. To prevent over pressurization, use an inflation device with manometer.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

1. Kramer, A., Ross, J., Gasparis, A.P. Chameleon™ PTA Balloon Catheter: A single device in managing thrombosed AV access. JVA. 2021; <https://doi.org/10.1177/11297298211027477>. Accessed June 23, 2021.

2. United States Renal Data System. 2019 USRDS Annual Data Report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2019.



Precautions

- Only physicians trained in the performance of PTA procedures should use the Chameleon™ device.
- The minimal acceptable sheath French size is printed on the product label. DO NOT attempt to pass the catheter through a sheath size smaller than that indicated on the product label.
- The recommended guide wire size is printed on the package label. DO NOT attempt to use the catheter without a guide wire or with a different size other than the one indicated on the label.
- If resistance is felt during post procedure withdrawal of the catheter, confirm that the balloon is fully deflated and only then remove the balloon catheter, the guide wire and the introducer sheath as a single unit.

Potential adverse reactions

Complications from a peripheral balloon dilatation procedure may include:

- Allergic reaction to drugs or contrast medium.
- Aneurysm or pseudo-aneurysm.
- Arrhythmias.
- Embolization.
- Hematoma.
- Hemorrhage, including bleeding at the puncture site.
- Hypotension / hypertension.
- Inflammation.
- Need for additional intervention.
- Occlusion.
- Pain or tenderness.
- Pneumothorax or Hemothorax.
- Sepsis / infection.
- Shock.
- Short term hemodynamic deterioration.
- Stroke.
- Thrombosis.
- Vessel dissection, perforation, rupture or spasm.

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