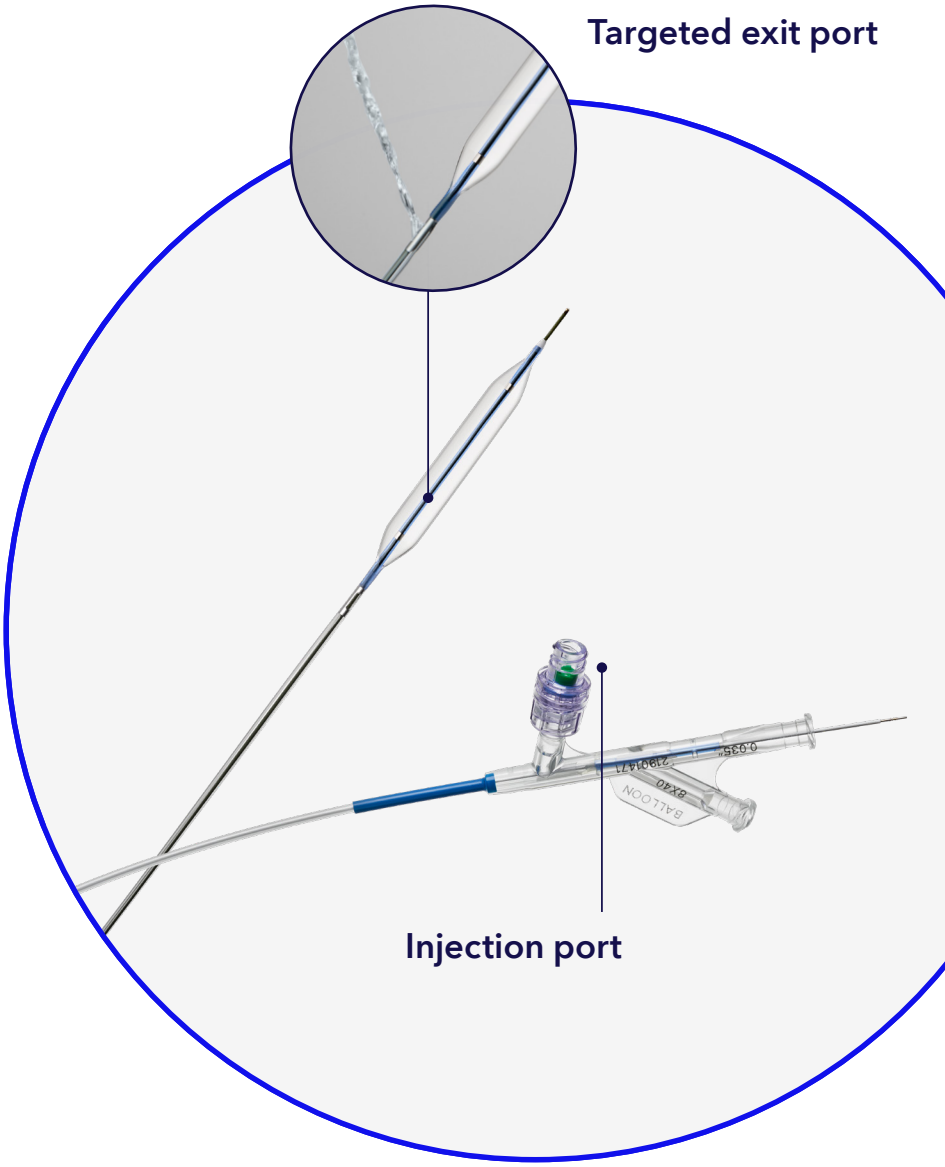
Medtronic

Chameleon™ PTA balloon catheter

PTA and injection. Combined.

Discover the power of multitasking

The Chameleon™ PTA balloon catheter uniquely combines high pressure balloon catheter and diagnostic catheter functionalities – enabling proximal injection of diagnostic fluids (like contrast media) and therapeutic fluids.



Versatility and efficiency

Visualize while injecting through the catheter – whether the balloon is inflated or deflated – all while maintaining wire position.

Perform multipurpose functions
Complete an entire procedure with both angioplasty and injection of diagnostic or therapeutic fluids.

Optimize use of contrast
Reduce contrast usage with precise treatment site delivery, compared to standard PTA.[1,2]

Reduce exchanges and procedure time
Perform angiograms directly through the Chameleon™ PTA balloon catheter.[1,2]

Minimize radiation exposure
Fewer device exchanges, decreased fluoro time, and increased operator distance from radiaton source support lower radiation exposure.[1,2]

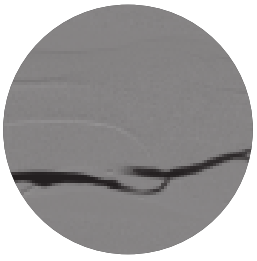
Enable hands-free reflux angiography
Eliminate manual compression and enhance operator safety performing reflux angiography with simultaneous venous outflow occlusion.

Promising clinical results with the Chameleon™ PTA balloon catheter

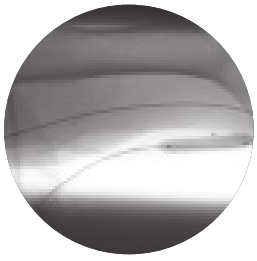
Case 1

Courtesy of Dr. Jeffrey Hoggard, Chapel Hill, North Carolina
Juxta-anastomotic stenosis of AV fistula
Chameleon™ PTA balloon catheter 8 x 40 mm

Retrograde approach

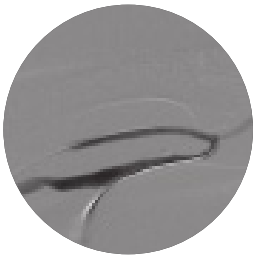


Juxta-anastomotic narrowing



Balloon inflation

Balloon inflation



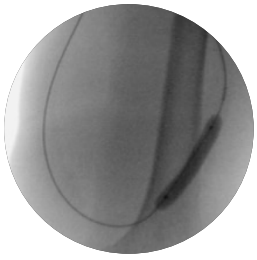
Final imaging through the side port of the Chameleon™ balloon catheter

Case 2

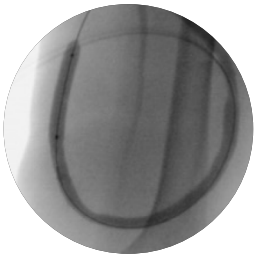
Courtesy of Dr. Robert Madden, West Springfield, Massachusetts
Upper Arm Loop Graft, Antegrade
Chameleon™ PTA balloon catheter 8 x 40 mm

Reflux angiography

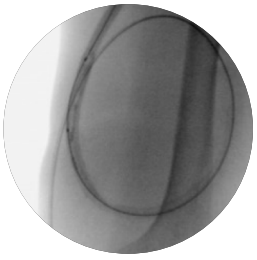
Balloon inflation



Balloon inflation



Hands-free reflux angioplasty through the inflated Chameleon™ balloon catheter



Outflow imaging through the deflated Chameleon™ balloon catheter

Available in a range of sizes

Catalog Number	Diameter (mm)	Balloon Length (mm)	Catheter Length (cm)	Sheath Size (F)	Nominal Pressure (atm)	Rated Burst Pressure (atm)	Guidewire (in)
CH05-40-75US	5	40	75	6	14	25	0.035
CH06-40-75US	6	40	75	6	14	25	0.035
CH07-40-75US	7	40	75	6	14	22	0.035
CH08-40-75US	8	40	75	6	14	22	0.035
CH09-40-75US	9	40	75	7	12	18	0.035
CH10-40-75US	10	40	75	7	12	14	0.035
CH12-40-75US	12	40	75	8	12	14	0.035

Important Safety Information
Please see Full Prescribing Information in the IFU.

Indications for Use
The Chameleon™ PTA balloon 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™ PTA balloon 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™ PTA balloon:

- 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. CO_2) 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.

Precautions

- Only physicians trained in the performance of PTA procedures should use the Chameleon™ PTA balloon.
- 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.

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

1. Crawford J, Kokkosis A, Kim P, Gasparis A, Labropoulos N. Fistuloplasty using a radiation-and-time-saving sheathless balloon catheter. *J Vasc Access.* 2019;20(3):276-280.
2. Crawford J, Gasparis A, Kim P, Jotwani M, Banerjee S, Labropoulos N. Procedural comparison of a standard PTA balloon for fistula and graft maintenance procedures with the novel Chameleon™ PTA balloon catheter. *J Vasc Access.* (2020 Dec 15). doi:10.1177/1129729820979479.

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