

# Iliac Recanalization With the Crosser® Catheter

A case-based view on retrograde and antegrade approaches to challenging iliac artery revascularizations.

BY A. GEORGE AKINGBA, MD, PhD, AND LUONA SUN, MD

Peripheral artery disease (PAD) can present with acute, chronic, or acute-on-chronic symptoms, although chronic symptoms represent the most common presentation of PAD. Chronic symptoms of PAD are often a result of stenotic, occlusive, or a combination of both types of atherosclerotic lesions. As a result, chronic total occlusions (CTOs) are frequently encountered during endovascular interventions and have been reported in up to 40% of patients with symptomatic PAD.<sup>1</sup> The treatment of CTOs is challenging for the endovascular interventionist because CTOs present technical difficulties with maintaining central lumen wire positioning after lesion traversal. In the past, standard guidewire techniques were frequently used for crossing total occlusions. A review of femoropopliteal subintimal angioplasty found treatment failures occurred approximately 10% to 25% of the time, the most common reason for failure being the inability to re-enter the true lumen beyond the distal cap.<sup>2,3</sup> Because of the increasing prevalence of fibrocalcified plaque or multilevel or long occlusive lesions, CTO crossing devices are receiving greater popularity for recanalizing CTOs. Before the advent of CTO crossing devices, the approach of most vascular specialists was to treat long CTOs with bypass surgery. With the availability of these devices, we can offer additional treatment options, particularly for patients where an open surgical approach may not be feasible or recommended.

The Crosser® Recanalization System is designed to cross CTOs of the peripheral vasculature. For infrainguinal CTO treatment, the Crosser® Catheter 14S and 14P (Bard Peripheral Vascular, Inc.) are designed to facilitate the intraluminal placement of conventional guidewires via athertectomy. The Crosser® Catheter 14S and 14P have a 1.1-mm titanium tip and are compatible with 0.014-inch guidewires. The Crosser® Generator includes a transducer, which has piezoelectric crystals that convert amplified alternating current into high-frequency vibrational energy that is transmitted to the catheter tip. This vibrational energy disrupts and crosses through fibrocalcific plaque, creating a channel

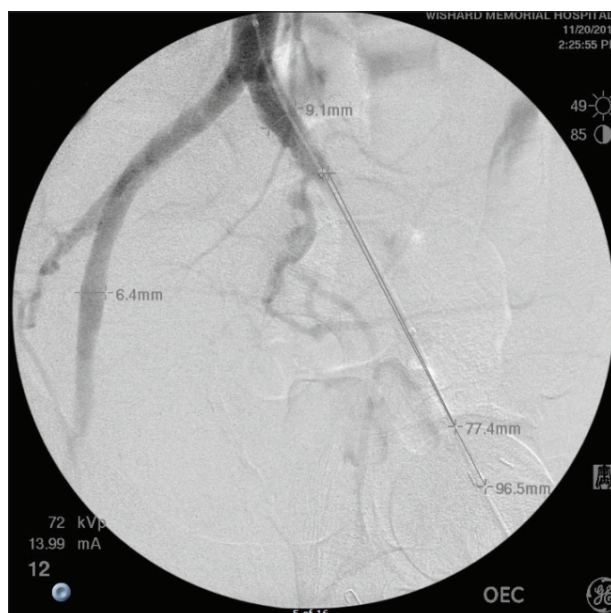
for subsequent therapies. The Crosser® Catheter 14S and 14P come in 106- and 146-cm working lengths, and given the small footprint of the Crosser® Catheter, it is appropriately sized for use in small vessels, such as the tibial vessels. We have also found the Crosser® Catheter particularly useful in treating focal lesions in larger vessels such as the common and external iliac arteries. We are presenting two cases of iliac artery recanalization with the Crosser® Catheter that would otherwise have been addressed with open surgical techniques.

## CASE ONE PRESENTATION

A 53-year-old man presented with a left great toe non-healing wound and associated history of left lower extremity claudication after walking one-half block. On physical examination, his left great toe nail bed had a chronic ulcer and no palpable pedal pulses bilaterally. His ankle-brachial indices (ABIs) were 0.73 on the right and 0.33 on the left, and a CT angiogram showed on the left he had external iliac artery (EIA), common femoral artery (CFA), and proximal superficial femoral artery (SFA) occlusions with above-knee popliteal reconstitution. Based on these clinical findings, the patient was scheduled for a left lower extremity hybrid revascularization of his arterial inflow in the form of a left femoral endarterectomy plus profundoplasty, left EIA atherectomy, and stenting.

## Description of Procedure

A vertical skin incision was made in the left groin. The left common femoral, superficial femoral, and profunda femoris arteries were exposed from the inguinal ligament to the primary branches of the profunda femoris artery. We then performed a left CFA and profunda femoris artery endarterectomy with a bovine patch repair in a standard fashion, after which we proceeded with the endovascular portion of this hybrid intervention. We used a 5-F micro-puncture sheath assembly to retrograde-cannulate the left CFA through the patched artery just above its bifurcation in order to have adequate purchase for a larger access



**Figure 1.** A postcrossing AIF angiogram demonstrating a long left common iliac artery CTO.

sheath. Under fluoroscopic guidance, we then upsized to a 7-F access sheath using the Seldinger technique. We could only insert a portion of the sheath into the CFA secondary to the EIA CTO. We then proceeded to engage the Crosser® Catheter 14P at the distal cap of our EIA CTO lesion. Under fluoroscopic guidance, we then activated and advanced the Crosser® Catheter in a retrograde fashion across the distal and proximal caps of the iliac CTO lesion terminating with our catheter tip in the distal aorta.

We then confirmed intraluminal placement of our wire by performing aortoiliofemoral (AIF) angiography (Figure 1), which demonstrated adequate opacification of the distal aorta and contralateral iliac artery system, as well as outflow into the left hypogastric artery. This image identified the long left common iliac artery CTO, and in the right anterior oblique magnified orientation, we were able to ascertain the critical dimensions of this left EIA lesion in order to select the appropriate-sized stents. Based on the length of the lesion, two self-expanding covered stents in the form of a 7- X 50-mm Viabahn™ Endoprosthesis (Gore & Associates) were selected for placement in an overlapping, telescoping fashion. The distal stent was placed first, with the most distal end at the level of the acetabulum. We then proceeded to telescope the more proximal end to the origin of the EIA in order not to cover the hypogastric vessel. This was done over a stiff V-18™ Guidewire (Boston Scientific Corporation).

A poststent angiogram was obtained, which showed improved opacification and flow through this segment with residual stenosis at the level of the inguinal ligament. We therefore placed a bare-metal self-expanding 7- X 40-mm



**Figure 2.** Completion angiogram showing normalized opacification through the iliac CTO.

stent at this location. Poststent angioplasty was performed with a 7- X 80-mm Dorado® PTA Catheter (Bard Peripheral Vascular, Inc.), and completion angiography was performed that showed improved flow and normalized opacification through this segment with no residual stenosis and maintenance of flow through the left hypogastric and contralateral iliac artery system (Figure 2). A left lower extremity runoff angiogram was then obtained, which demonstrated adequate flow through the patch and profunda femoris artery branches in the proximal thigh. In the distal thigh, it showed reconstitution of the above-knee popliteal artery through large collaterals. The patient was noted to have an adequately opacified popliteal artery with an adequately opacified tibioperoneal trunk.

At 1- and 3-month follow-up, the patient was noted to have improvement in his claudication and complete left toe ulcer healing. His ABIs had improved from 0.33 (preoperative) to 0.70 at his 3-month postoperative evaluation, while his duplex study demonstrated a patent left EIA stent.

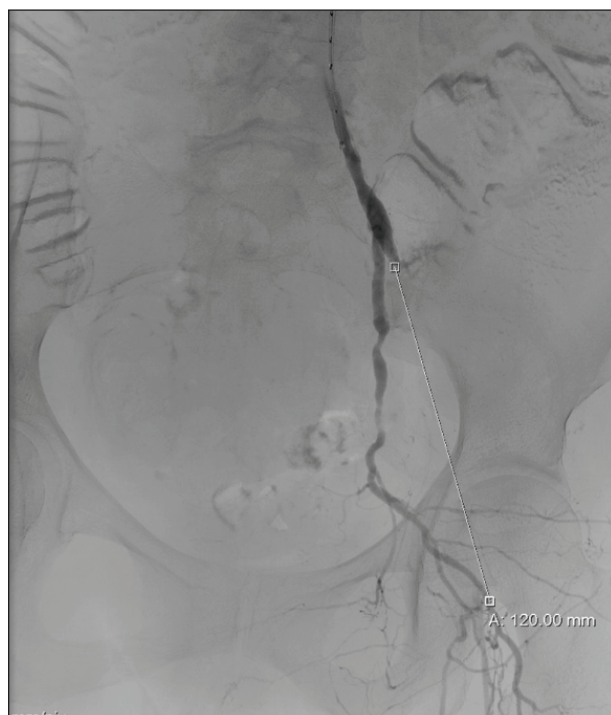
## CASE TWO PRESENTATION

A 50-year-old woman with a history of anal squamous cell carcinoma status post neoadjuvant chemotherapy radiation followed by an abdominoperineal resection with an end colostomy presented with bilateral lower extremity rest pain and left great toe tissue loss. Her abdominoperineal resection procedure was complicated by wound dehiscence and a wound infection; therefore, the patient was noted to have a hostile abdomen. On physical exam, her bilateral femoral pulses were not palpable, and she had left great toe gangrene with adjacent rubor. ABIs were 0.33

on the right and 0.22 on the left. CT angiography showed the distal aorta and common iliac arteries were patent, as well as a patent origin of both external iliac arteries. The rest of the external iliac arteries were occluded with distal reconstitution at the level of the femoral arteries and three vessel runoffs bilaterally. Based on this clinical evidence, the patient was scheduled for an AIF angiogram and endovascular intervention through a left brachial access approach.

### Description of Procedure

A 4-cm longitudinal incision was made at the level of the distal upper arm over the brachial pulse. The brachial artery was identified and exposed for 4 cm. We then proceeded to retrograde-cannulate the left brachial artery under direct visualization with a 5-F micropuncture sheath assembly with resultant good backflow of arterial blood. We then exchanged for a 5-F access sheath, selectively cannulated the distal aorta, and obtained an AIF angiogram. We exchanged the 5-F access sheath for a 7-F, 70-cm Ansel guide sheath (Cook Medical), which was advanced over a stiff wire into the distal aorta. The left common iliac artery was selectively cannulated, and a left iliofemoral angiogram in the right anterioposterior oblique orientation was then obtained in order to adequately define our proximal and distal CTO caps (Figure 3). This enabled us to obtain the critical dimensions of our CTO lesion. A Crosser Catheter® 14S was engaged at the proximal CTO cap in the proximal external



**Figure 3.** A left iliofemoral angiogram to define the proximal and distal CTO caps.

iliac artery (EIA), and under fluoroscopic guidance, we activated and advanced the Crosser® Catheter in an antegrade fashion across the proximal and distal caps of the left EIA CTO lesion, terminating this portion of the procedure with our catheter tip in the patent lumen of the left CFA. The left EIA and CFA lesions were predilated with a 6-mm X 120-mm Dorado® Balloon, and a postangioplasty angiogram was obtained that showed markedly improved flow and opacification through this treated segment. Based on our intent to primarily stent the left EIA CTO, we deployed a 6-mm X 80-mm stent across the left EIA lesion. The stent was postdilated with a 6-mm X 120-mm Dorado® Balloon, and a poststent angiogram was obtained that showed markedly improved flow and normalized opacification through the EIA and CFA (Figure 4A). A runoff angiogram demonstrated adequate flow and normal opacification of the infrainguinal arteries down to the ankle (Figure 4B).

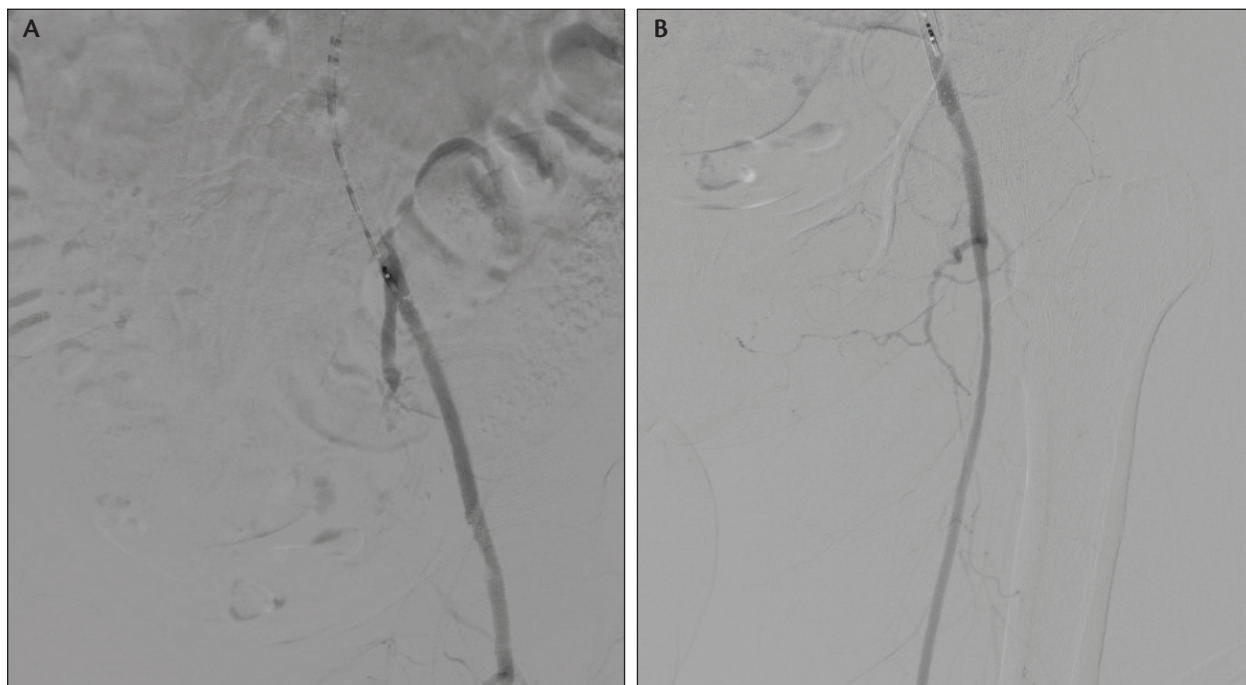
After successful revascularization of the left lower extremity, we turned our attention to address the right EIA CTO lesion. In a similar fashion, a right iliofemoral angiogram was obtained to assess the critical dimensions of the right EIA and CFA lesion (Figure 5). We then proceeded to utilize the Crosser® Catheter 14S in the same antegrade fashion to traverse the right EIA and right CFA, as well as the proximal right SFA. A postcrossing traversal angiogram confirmed the device was intraluminal in the proximal right SFA. In a similar fashion to the contralateral side, the right EIA lesion was predilated and stented with a 6-mm X 80-mm stent. The stent was postdilated, and a poststent angiogram was obtained that showed markedly improved flow and normalized opacification through the EIA and CFA, as well as the proximal SFA segment (Figure 6). A completion angiogram for the right lower extremity was obtained, which showed adequate opacification of the right SFA in the proximal thigh as well as at the level of the distal thigh and above-knee popliteal artery (Figure 7).

At the patient's most recent clinic evaluation (1 month postoperative), she had complete resolution of rest pain and was now ambulating. Her ABIs had improved to normal (at 1+ bilaterally).

### DISCUSSION

Revascularization of CTOs can be hindered by failure to cross the lesion due to a variety of factors, such as the inability to maintain the guidewire in the true lumen or inability to re-enter the true lumen with the guidewire.<sup>4,5</sup> Attempts to revascularize heavily calcified CTOs with traditional guidewire and balloon technologies fail in approximately 20% of cases.<sup>4</sup> In our experience, iliac artery CTOs provide a greater challenge for lesion wire traversal, as these vessels are fairly tortuous and often have a larger plaque burden compared to infrainguinal vessels. As such, knowledge of

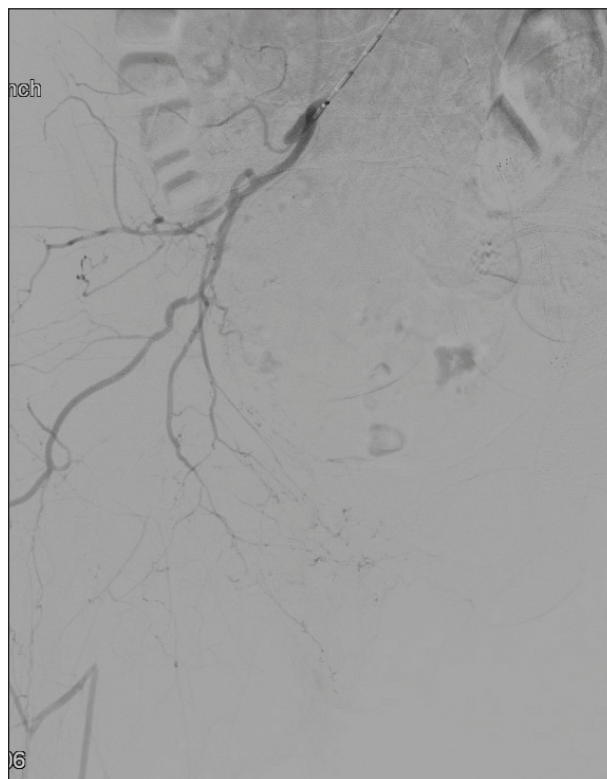




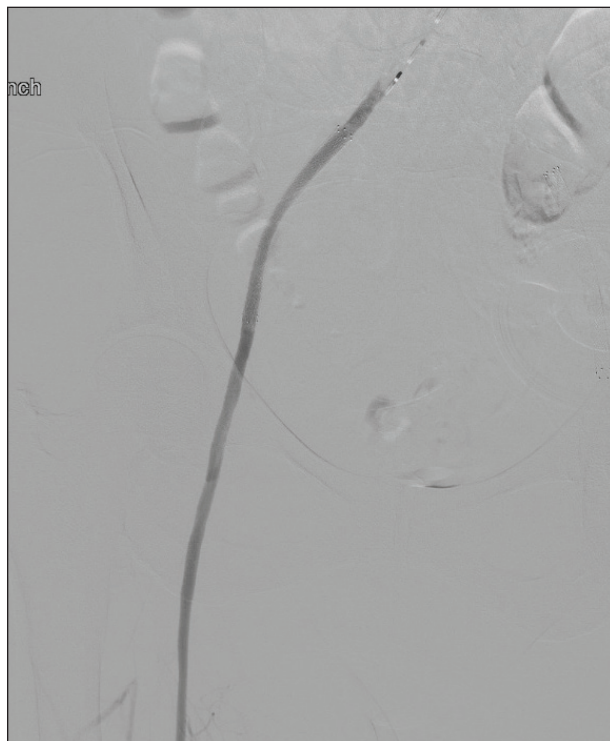
**Figure 4.** Completion left iliofemoral angiogram showing improved flow and normalized opacification through the EIA (A) and CFA (B) with good proximal SFA runoff.

the course of the iliac vessel as well as the orientation of the proximal and distal caps is very useful in improving the success of lesion traversal using the Crosser® Catheter. A CTO crossing device such as the Crosser® Recanalization System is designed to drill through the fibrocalcified lesion.<sup>6</sup> The addition of an angled 7-F Sidekick® Support Catheter (Bard Peripheral Vascular, Inc.) allows us to engage the proximal or distal cap in a perpendicular fashion to maximize central lumen Crosser® Catheter traversal of these tortuous vessels. Finally, after traversal of our distal cap, a tapered support catheter is used to dilate the recanalized channel and a run-off angiogram is obtained to ascertain appropriate re-entry into the center lumen of our distal target vessel. We then proceed with lesion pre- and postdilatation in addition to primary stenting of the iliac vessel.

Based on the cases we have presented and multiple other CTO crossing and atherectomy cases performed, we have found that an effective recanalizing device such as the Crosser® Catheter is a very useful tool for the vascular interventionist. Understanding the vessel course, location of collaterals, and CTO (proximal and distal) cap orientation is very important and allows the vascular interventionist to adjust the procedural technique accordingly in order to increase the likelihood of procedural technical success. Currently, we have also restricted our use of guidewire probing to only lesions that show evidence of a string-sign so as not to create a subintimal dissection plane, which, if



**Figure 5.** Right iliofemoral angiogram showing EIA and CFA CTO lesions.

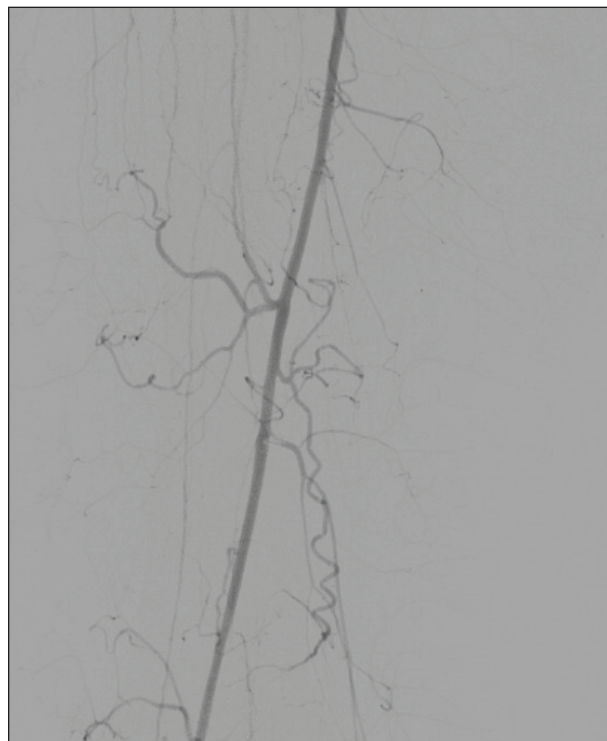


**Figure 6.** Right iliofemoral angiogram showing normalized opacification through the EIA and CFA, as well as proximal SFA segment.

the interventionist is unsuccessful in re-entering the center lumen, likely becomes the path the Crosser® Catheter also takes, thereby eliminating our concurrent opportunity for successful center lumen lesion traversal. Our use of the Crosser® Catheter as a first-line therapy approach has resulted in our very high technical success rates of CTO traversal, irrespective of the arterial tree supplying the lower extremity.

## CONCLUSION

The emergence of more sophisticated CTO crossing devices has increased the ability to recanalize some of the most challenging occlusions, such as highly calcified lesions in small- and large-caliber peripheral arteries using an antegrade or retrograde approach. The combination of the small-caliber Crosser® Catheter tip with an angled support catheter has allowed us to successfully tunnel through severely calcified plaque within the iliac vasculature, while maintaining central lumen positioning across our proximal and distal CTO caps. Further experience with these types of challenging lesions by multiple users and randomized controlled trials will be required in order to determine the long-term benefits and cost-effectiveness of crossing devices. ■



**Figure 7.** A runoff angiogram for the right lower extremity showing adequate opacification of the right SFA in the proximal and distal thigh.

*A. George Akingba, MD, PhD, is an Assistant Professor of Surgery, Biomedical Engineering, and Medicine, Indiana University School of Medicine in Indianapolis, Indiana. He has disclosed no financial interests related to this article. Dr. Akingba may be reached at (317) 880-3552.*

*Luona Sun, MD, is a research fellow for the Krannert Institute of Cardiology, Indiana University, School of Medicine, Indianapolis, Indiana. Dr. Sun has disclosed no financial interests related to this article.*

*The opinions and clinical experiences presented herein are for informational purposes only. The results from this case study may not be predictive for all patients. Individual results may vary depending on a variety of patient specific attributes. The physicians have prepared these case studies at the request of Bard Peripheral Vascular, Inc. for Bard's further use and distribution.*

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## SAFETY INFORMATION

Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contra-indications, Warnings, Precautions, Adverse Events, and Operator's Instructions. Caution: Federal Law (USA) restricts these devices to sale by or on the order of a physician.

### CROSSER® CTO RECANALIZATION CATHETER

#### INDICATIONS FOR USE

The Crosser® Recanalization System is indicated to facilitate the intraluminal placement of conventional guidewires beyond peripheral artery chronic total occlusions via atherectomy. The Crosser® Catheter is only intended for use with the Crosser® Generator. Refer to the Crosser® Generator Manual of Operations for proper use.

#### CONTRAINDICATIONS

The device is contraindicated for use in carotid arteries.

#### WARNINGS AND PRECAUTIONS

- Never advance or withdraw the Crosser® Catheter without proper fluoroscopic guidance.
- It is not recommended to use the Crosser® Catheter over wires which have polymer-jacketed distal ends.
- When using the Crosser® Catheter 14S or 14P with the MicroSheath® XL Support Catheter Tapered, the Crosser® Catheter can be advanced approximately 15cm from the tip of the support catheter before resistance is encountered due to the taper on the Crosser® Catheter aligning with the taper on the support catheter. A taper lock-up marker (single marker on the Crosser® Catheter shaft) is located 127cm from the distal tip for the 146cm Crosser® Catheter and 87cm from the distal tip for the 106cm Crosser® Catheter. The taper lock-up marker can be used as an indicator that the tapers on the catheters are nearing alignment; advance the Crosser® Catheter slowly. Do not continue to advance the Crosser® Catheter if resistance is encountered.
- When using the Crosser® Catheter in tortuous anatomy, the use of a support catheter is recommended to prevent kinking or prolapse of the Crosser® Catheter tip. Kinking or prolapse of the tip could cause catheter breakage and/or malfunction.

### SIDEKICK® AND USHER® SUPPORT CATHETERS

#### INDICATIONS FOR USE

The Sidekick® and Usher® Support Catheters are single lumen catheters intended to create a pathway for other devices in the peripheral vasculature.

#### CONTRAINDICATIONS

The Sidekick® and Usher® Catheters are contraindicated for use with cutting/scoring balloons, pediatrics, neonatal and neurovascular patients.

#### WARNINGS AND PRECAUTIONS

- When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Movement of the product without fluoroscopic guidance may result in damage to the product or vasculature or cause vessel perforation.
- Manipulating or torquing a product against resistance may cause damage to the product or vasculature or cause vessel perforation. Never advance, withdraw or torque a catheter which meets resistance.
- Verify compatibility of the product's inner and outer diameters and lengths with other devices before use.

- Refer to package label for tip shape for the Sidekick® and Usher® Catheters. Do not attempt to manipulate or re-shape the tip configurations.

### VASCUTRAK® PTA DILATATION CATHETER

#### INDICATIONS FOR USE

The Vascutrak® PTA Dilatation Catheter is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also recommended for post dilatation of balloon expandable stents, self-expanding stents, and stent grafts in the peripheral vasculature.

#### CONTRAINDICATIONS

The Vascutrak® PTA Catheter is contraindicated where there is the inability to cross the target lesion with a guidewire and for use in the coronary or neuro vasculature

### DORADO® PTA DILATATION CATHETER

#### INDICATIONS FOR USE

Dorado® Balloon Dilatation Catheters are recommended for Percutaneous Transluminal Angioplasty (PTA) of the renal, iliac, femoral, popliteal, tibial, peroneal, and subclavian arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also recommended for post-dilatation of balloon expandable and self expanding stents in the peripheral vasculature. This catheter is not for use in the coronary arteries.

#### CONTRAINDICATIONS

None known

### LIFESTENT® VASCULAR STENT SYSTEM

#### INDICATIONS FOR USE

The LifeStent® Vascular Stent System is intended to improve luminal diameter in the treatment of symptomatic de-novo or restenotic lesions up to 240mm in length in the native superficial femoral artery (SFA) and proximal popliteal artery with reference vessel diameters ranging from 4.0-6.5mm.

#### CONTRAINDICATIONS

The LifeStent® Vascular Stent System is contraindicated for use in:

- Patients with a known hypersensitivity to nitinol (nickel, titanium), and tantalum.
- Patients who cannot receive recommended anti-platelet and/or anti-coagulation therapy.
- Patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or stent delivery system.

#### ADVERSE EVENTS

As with most percutaneous interventions, potential adverse effects include: Bleeding which may require transfusion or surgical intervention, Hematoma, Perforation, Dissection, Guidewire entrapment and/or fracture, Hypertension / Hypotension, Infection or fever, Allergic reaction, Pseudoaneurysm or fistula Aneurysm, Acute reclosure, Thrombosis, Ischemic events, Distal embolization, Excessive contrast load resulting in renal insufficiency or failure, Excessive exposure to radiation, Stroke/CVA, Restenosis, Repeat catheterization / angioplasty, Peripheral artery bypass, Amputation, Death or other bleeding complications at access site.