A patient presented with a Rutherford class V, nonhealing wound in the distribution of the posterior tibial (PT) artery. Angiography was performed and showed severe tibial disease (Figure 1). Multivessel tibial CTOs over 300 mm in length were also noted. The procedure was initiated with an antegrade selective angiogram showing severe proximal CTOs of the anterior tibial (AT) artery and the PT.

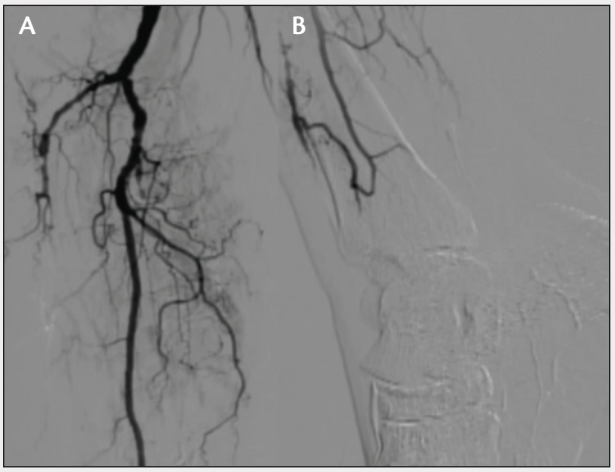

Figure 1. Antegrade selective angiogram showing severe proximal CTOs of the AT and PT arteries (A). Poor distal tibial runoff, a common finding in CLI patients (B). Note the absence of reconstitution of the PT and the faint reconstitution of the AT. The only artery with intact flow is the peroneal artery with intact anterior and posterior communicating arteries.

Poor distal tibial runoff and nearly absent flow in the pedal circulation are common in patients with critical limb ischemia. Note the absence of reconstitution of the PT and the faint reconstitution of the AT, making a decision to treat this type of anatomy very challenging, especially with the absence of target reconstitution of the distal CTO. The only artery with some intact flow was the peroneal artery, with intact anterior and posterior communicating arteries but no retrograde or antegrade flow into the PT artery. We chose to use the Crosser® Catheter due to our success rate and level of comfort with this device. In particular, this is the type of CTO where an operator will need to trust in the mechanism of action of the device. Figure 2 highlights this crucial point to remember while crossing the CTO cap with the Crosser® Catheter. Do not get discouraged if there is a lack of immediate forward movement of the Crosser® Catheter. As Figure 2 shows, the Crosser® Catheter penetrates the CTO cap, which can be seen if EVUS is being used.

With progressive advancement of the Crosser® Catheter into the complex long calcified CTO, the combination of mechanical disruption and cavitation allows the device to cross the disparate parts of the CTO. After successful revascularization of a long, 300-mm CTO, final fluoroscopic angiography was performed with direct runoff to the foot, which continues to be the gold standard during infrainguinal revascularization (Figure 3).

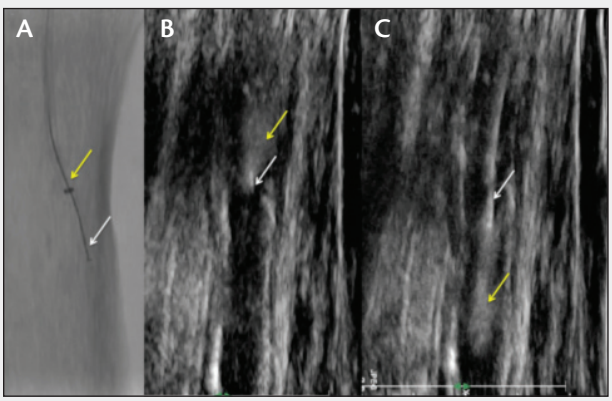

Figure 2. Fluoroscopic evaluation of an activated Crosser® Catheter (white arrow) with its angled Sidekick® Support Catheter (yellow arrow) (A). Fluoroscopy tends to provide no visual feedback, as shown here. Initial activation of the Crosser® Catheter (white arrow) at the cap initiates the generation of cavitation-induced microbubbles (yellow arrow), which are initially reflected back from the highly resistant CTO cap (B). The Crosser® Catheter (white arrow) advances through the CTO cap and the cavitation within the irrigation (yellow arrow) advances in front of the catheter (C).

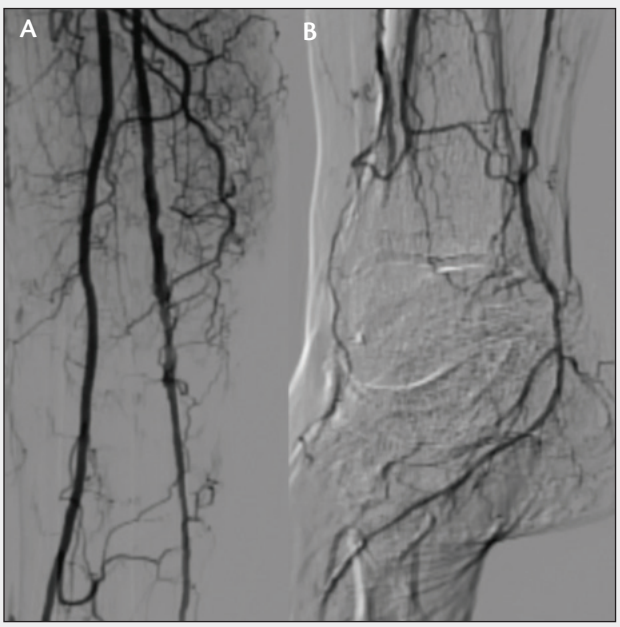

Figure 3. Postrevascularization of the PT artery with intact flow proximal, mid, and distal (A). Pedal runoff showing now intact pedal flow into the distribution of the PT artery (B).

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.