

Treating CLI in Calcified, Tortuous Below-the-Knee Anatomy With the Peripheral Rotablator™ Atherectomy System

BY SCOTT M. BRANNAN, MD, AND KEITH GOSS, DPM

The Peripheral Rotablator™ Rotational Atherectomy System (Boston Scientific Corporation) is uniquely well-suited for use in distal tibial and below-the-knee arterial reconstructions in patients with densely calcified, severely stenosed critical limb ischemia. Due to its flexibility, small caliber, and front-end cutting, the system can achieve effective therapy in diminutive and tortuous arteries that other mechanical atherectomy devices often cannot even approach.

The patient population that my partner, Dr. Keith Goss, and I work with at the First Nations Limb Preservation Foundation is primarily Native American with diabetic foot ulcers and critical limb ischemia. Due to the severity of peripheral vascular disease in this subset of patients, unique strategies are needed to address the densely calcified infrapopliteal disease that characterizes the majority of the Native Nations' peripheral vascular problems in the modern era.

In 2014, my partner and I performed the first angiogram at a Native Nations Hospital. Our first patient presented with tandem occlusions of the anterior tibial artery and a distal focal occlusion of the posterior tibial artery, each of which yielded to crossing with a V-18™ ControlWire™ (Boston Scientific Corporation) and a 0.018-inch support catheter. At that time, we were not using atherectomy routinely. Over the ensuing months, we noted that even those patients who responded robustly to prolonged angioplasty tended to have relatively brief periods of luminal patency, and on our follow-up duplex arterial images, they would frequently meet target lesion revascularization criteria within 90 days. We began to employ atherectomy as a first-line modality for treatment of densely calcified infrapopliteal atherosclerotic stenosis.

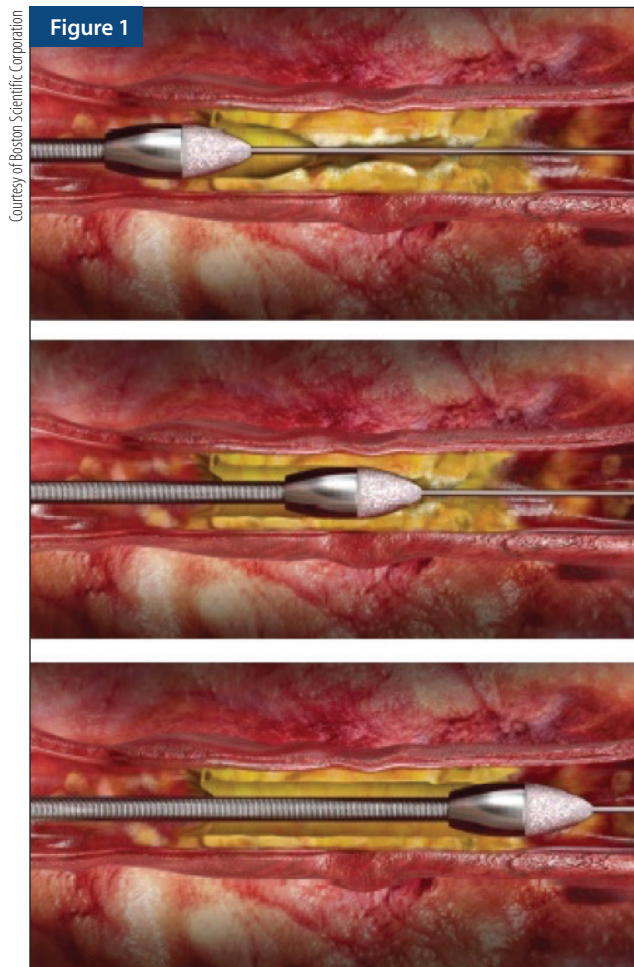
Initially we used orbital atherectomy, which achieved acceptable results, but was associated with a small num-

ber of embolization events. We then began to utilize the Peripheral Rotablator Atherectomy System for densely calcified tibial artery stenosis, lesions at or near the ankle, or lesions below the ankle that were extremely resistant to passage of an appropriately sized angioplasty balloon. We encountered great success with Rotablator Atherectomy in terms of plaque remodeling and reestablishment of a lumen through densely occluded segments to allow for passage of an appropriately sized angioplasty balloon. The ease of use of the device was also a significant contributor to its acceptance within our practice. The nitrogen tank and the separate power source/converter for the nitrogen gas posed a small problem in terms of floor space. However, utilizing a single cart and changing the bed position to bring the nitrogen tank closest to the treatment side helped to resolve those initial room configuration issues.

ROTABLATOR MECHANISM OF ACTION

The Rotablator Atherectomy System employs a diamond-coated burr that is capable of spinning above 200,000 rpm and ablating calcified plaque within moderate to severely diseased vessels to create a concentric lumen. The procedure is guided through vessels using a 0.009-inch guidewire via real-time fluoroscopy, and requires a connection to the console, compressed nitrogen or air supply, as well as an IV fluid mix. Once the device encounters stenosis within the vessel, a foot-pedal is used to start rotation prior to each pass, and the ablated particles are eventually phagocytized by the reticuloendothelial system. According to studies among coronary literature performed in the last 20 years, these plaques measure approximately 5 µm when correct technique is used, meaning that devices for embolic protection are not used, as their pore sizes are in the range of 100 µm.

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**Figure 1**

Courtesy of Boston Scientific Corporation

A great benefit of the Rotablator Atherectomy System's design is the front-cutting diamond burr (Figure 1). While rotating on the RotaWire™ (Boston Scientific Corporation), this front-end cutting feature engages the lesion directly without the need for predilatation. This subsequently saves the patient's vessel from barotrauma, which can be more of a concern with other atherectomy devices. Furthermore, average run times are around 3 to 4 minutes per vessel, even in lesions that are long and diffuse. In our experience, the Rotablator's speed and effectiveness allowed it to remove moderate to severe plaque with minimal injury to the vessel wall in order to deliver excellent patient outcomes.

In this article, we present three cases from our center that illustrate the utility of the Rotablator Peripheral Atherectomy System in these challenging anatomical presentations.

CASE #1

A 49-year-old Native American man presented with type 2 diabetes and critical limb ischemia. One year

previously, he had a below-the-knee amputation on the right side for a nonhealing ulcer and osteomyelitis after stepping on a nail. He was referred to our institution for a new nonhealing diabetic foot ulcer on the left side at the plantar surface overlying the fourth metatarsal head. Preprocedural ankle-brachial index was within normal limits on the left side, measuring 1.31. Arterial duplex examination demonstrated biphasic flow within the posterior tibial artery at the level of the medial malleolus with a velocity of 32 cm/s. Given the patient's history of contralateral amputation and the focal distribution of his nonhealing ulcer within the lateral plantar angiosome, the decision was made to perform further investigation with selective angiography.

Technique

The left common femoral artery was accessed from an antegrade approach, and initial images were obtained through the 4-F micropuncture sheath. After ruling out significant femoropopliteal disease, a 5-F X 55-cm sheath was advanced down to the level of the below-the-knee popliteal artery. Detailed infrapopliteal angiography was performed through the selective sheath, showing occlusion of the lateral plantar branch (Figure 2). A V-18 ControlWire (Figure 3) and 2.5-mm X 100-mm Sterling™ angioplasty balloon (Boston Scientific Corporation) were used to cross the occluded lateral plantar branch, followed by retrograde selection of the dorsalis pedis artery for completion of the pedal plantar loop.

Exchange was then made for the 0.009-inch RotaWire. Endovascular ultrasound was performed over the RotaWire with a 0.014-inch probe through the lateral plantar branch, confirming the angiographic findings of segmental occlusion. Next, Rotablator Atherectomy

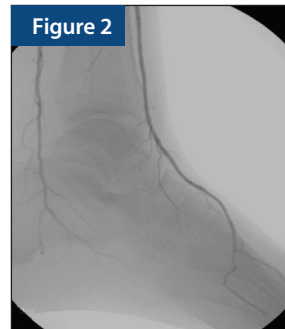
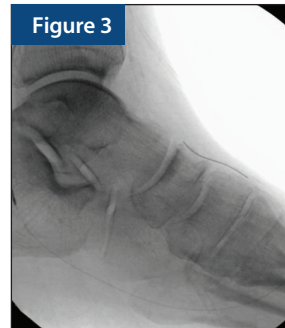
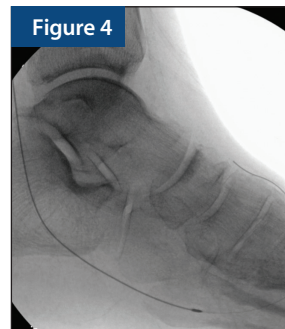
Figure 2**Figure 3****Figure 4**

Figure 5

S ...
 T -
 U ...
 V ...-
 W ...
 X ...-
 Y ...-
 Z ...-

was performed with a 1.25-mm burr through the lateral plantar artery, utilizing the "Morse code" technique (Figure 4). When using the Rotablator in the distal tibial arteries or below the ankle, one of the most important technical necessities is to maintain brief intervals of short-segment, staccato forward pressure

followed by slightly more prolonged intervals of burr retraction. The cadence is that of a "V" in Morse code (dot, dot, dot, dash...dot, dot, dot, dash) (Figure 5).

The atherectomy device was removed and replaced with a 2.5-mm X 100-mm Sterling angioplasty balloon for a 3-minute inflation around the pedal plantar loop (Figure 6). Completion angiography showed successful restoration of the lateral plantar branch and pedal plantar loop (Figure 7), with markedly improved soft tissue opacification at the site of the nonhealing ulcer.

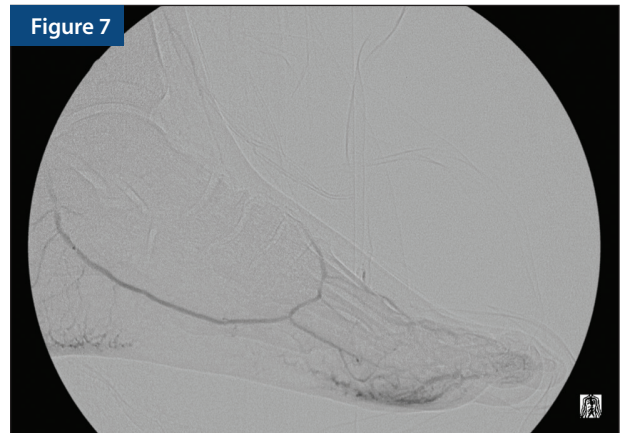
Due to its flexibility, small profile, and front-end cutting capabilities, the Rotablator System achieves effective atherectomy in calcified, diminutive, and tortuous arteries. The challenge of the small profile, however, is the requirement of a 0.009-inch RotaWire as the deployment rail. The pushability of the wire is consistent with its diminutive caliber and can make distal wire placement challenging, even in the presence of a distally positioned support catheter. When completing the pedal plantar loop, we encounter not only a 180° turn in the anterior-posterior axis, but two consecutive 90° turns in the craniocaudal plane and at least one 90° short segment arc in the medial lateral plane. These consecutive multiplanar anatomic turns result in accumulation of greater additive friction during wire passage through the larger catheter size. The tip of the RotaWire requires a 0.012-inch lumen, but the body of the wire is 0.009-inch. The size difference between the internal diameter of a standard 0.014-inch support catheter and the 0.009-inch wire requires a more delicate handling. Priming the catheter lumen with 1 mL of Rotaglide (Boston Scientific Corporation) can markedly reduce the amount of friction between the mismatched catheter/wire combination and assists in wire passage around tight distal turns.

In our treated population, we noticed that any ulcer that involves the heel has a much higher likelihood of progressing to amputation, so we do put an emphasis on the posterior tibial artery and the plantar branches. The Rotablator device was easily able to negotiate through the tortuous distal posterior tibial artery down into the

Figure 6



Figure 7



plantar branches, and we achieved an excellent result after Rotablator atherectomy and prolonged balloon angioplasty.

CASE #2

A 53-year-old Native American man from the Akimel O'odham tribe presented from the wound clinic with a moist, gangrenous, putrid ischemic ulcer at the medial aspect of the right heel within the arterial distribution of the right posterior tibial artery. He had type 2 diabetes complicated by end-stage renal disease, hypertension, chronic heart failure with severe orthopnea, and a previous right below-the-knee amputation.

The patient was referred for limb salvage. Given his inability to maintain a recumbent position, the decision was made to perform the procedure from a retrograde pedal approach with ultrasound-guided access of the anterior tibial artery before crossover of the tibial bifurcation into the affected posterior tibial artery. This was followed by recanalization, atherectomy, and angioplasty.

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Technique

A number of our Native American patients have elevated BMI with central distribution, as evidenced by a waist-to-thigh ratio > 3.5 in approximately 25% of our patients. For some patients, access to the groin, particularly from the antegrade approach required for distal tibial intervention, is extremely limited. For these patients and for those with orthopnea, a solitary pedal access site for diagnosis and treatment is often advantageous.

Most agree that treating from an antegrade approach in the tibials is the safest and most effective method. In order to satisfy the patient's need for pedal access, while at the same time maintaining preference for arterial intervention from antegrade, we use an up-and-over technique at the popliteal bifurcation level, which we refer to as the *Switchback* (Figures 8 and 9). When employing the Switchback technique, the operator achieves retrograde access into the tibial artery that is not in the angiosome of the wound. From that access point, the catheter and wire are advanced to the level of the popliteal bifurcation, where exchange is made for a 4-F Mini RIM catheter (Merit Medical Systems Inc). The Mini RIM is used to cross the popliteal artery bifurcation into the artery that supplies the most severely diseased angiosome. The unique crossing profile and flexibility of the Rotablator atherectomy catheter allowed it to cross over this relatively tight bifurcation without dislodging the wire cephalad and achieved effective atherectomy in the target vessel.

In order to target the far distal posterior tibial artery for treatment, the Switchback technique was decided upon, and the dorsalis pedis artery was accessed under ultrasound guidance with a micropuncture technique, followed by placement of a 4-F outer diameter and 5-F inner diameter Glidesheath Slender introducer sheath (Terumo Interventional Systems). After sheath placement, 600 mcg of nitroglycerin was instilled, and the patient was systemically heparinized with 6,000 units. The side arm was then attached to a continuous infusion of TAMI solution in order to minimize thrombosis and spasm. A V-18 ControlWire and 90-cm, 0.018-inch Rubicon™ Support Catheter (Boston Scientific Corporation) were used to select the right common iliac artery. Right lower extremity runoff angiography was performed in overlapping stations.

Due to suboptimal contrast opacification of the larger central arteries, pullback endovascular ultrasound evaluation was then performed from the common iliac artery through the distal anterior tibial artery to better characterize the morphology and severity of the atherosclerosis. IVUS showed calcific atherosclerotic disease in all visualized segments, but no focal flow-limiting stenosis



Figure 8



Figure 9

through the iliofemoral or femoral popliteal segments. Tandem 40% calcified stenoses of the proximal anterior tibial artery were noted.

Exchange was made over a Benson wire for a 5-F mini RIM catheter, which was used to select the posterior tibial artery origin. Following origin selection, a V-14 ControlWire was then used to select the posterior tibial artery (Figure 8). The V-14 ControlWire was advanced down to the level of the common plantar artery. Endovascular ultrasound of the right posterior tibial artery was then performed, showing multifocal critical stenoses down to the level of the ankle, which was densely calcified (Figure 9). Wire exchange was then made through a 0.018-inch, 3.5-mm X 100-mm Sterling angioplasty balloon catheter for a 0.009-inch RotaWire.

Rotablator Atherectomy was performed antegrade through the stenotic segments of the posterior tibial artery from the switchback retrograde sheath access in the anterior tibial artery (Figure 10) with a 1.5-mm burr, followed by angioplasty with a 3.5-mm balloon in an overlapping fashion.

Repeat endovascular ultrasound of the poste-

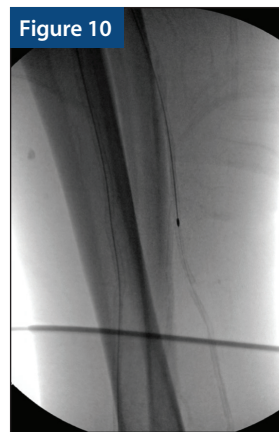


Figure 10

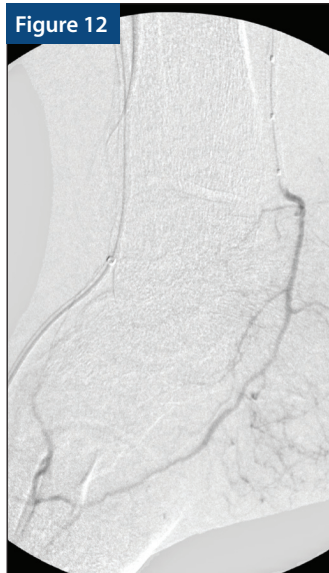


rior tibial artery demonstrated successful restoration of normal luminal caliber and markedly improved flow on the Chroma flow imaging. A completion angiogram confirmed these findings with markedly improved velocity of opacification through the posterior tibial artery (Figures 11 and 12).

The vascular access sheath was removed from the retrograde anterior tibial artery access site and manual compression was applied until hemostasis was achieved. The patient tolerated the procedure well.

CASE #3

A 56-year-old woman presented with bilateral heel and plantar surface rest pain. She had a history of type 2 diabetes mellitus for over 20 years, hyperlipidemia, and a body mass index of 52.3. The plantar surface of the right fifth metatarsal head was calloused and there was a focal shallow ulcer of the right heel. There were



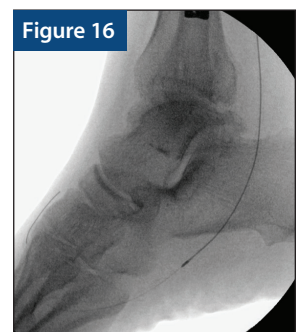
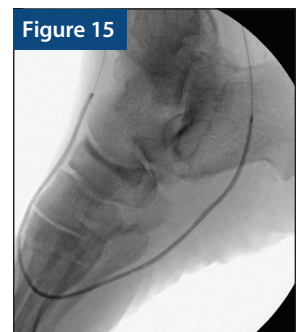
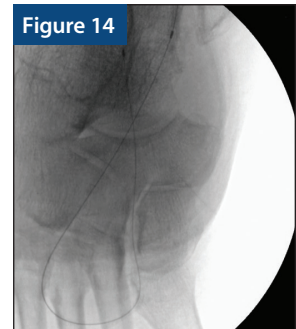
nonpalpable bilateral posterior tibial artery pulses, but monophasic Doppler signals were obtained, and there were palpable bilateral dorsalis pedis artery pulses.

Technique

Antegrade right common femoral artery access was achieved, and a 6-F X 25-cm sheath was advanced over a wire into the distal right superficial femoral artery, where low-dose right lower extremity angiography was performed (Figure 13). Endovascular ultrasound was then performed with a 0.014-inch probe.

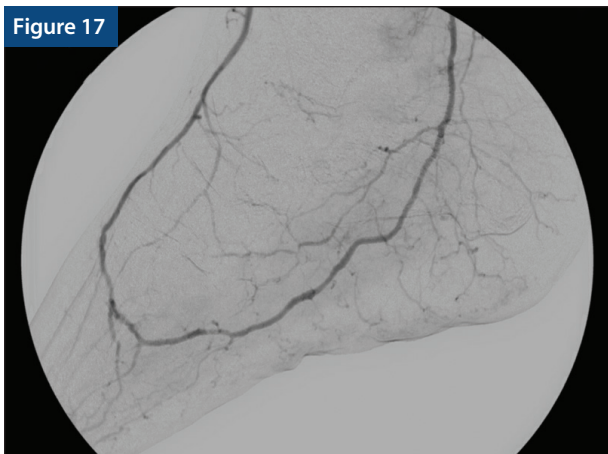
Imaging showed sluggish runoff through the posterior tibial artery, with an occluded lateral plantar artery and discontinuous pedal plantar loop. Single-vessel dominant runoff to the foot was provided by the anterior tibial artery, however, the distal dorsalis pedis artery did not opacify (Figure 14). The peroneal artery was diminutive but patent to the ankle. Fixation hardware was seen within the proximal tibia at the level of the tibial plateau, and also at the distal fibula (Figure 15). Focal hyperemia was seen at the location of the heel wound.

Utilizing a 2.5-mm X 100-mm Sterling balloon catheter and a V-18 ControlWire, the common plantar, lateral plantar, and distal segment of the deep perforating branch of the dorsalis pedis were successfully recanalized, and exchange was made for the 0.009-inch RotaWire. Atherectomy was then performed with a 1.25-mm Rotablator Atherectomy device through the lateral plantar branch, common plantar, and distal posterior tibial artery (Figure 16). Arterial dilation was then performed with a 2.5-mm X 150-mm Coyote™ balloon (Boston Scientific Corporation) advanced over the RotaWire. Postintervention imaging demonstrated successful restoration of the pedal plantar loop and improved soft tissue perfusion, most notably through the hindfoot



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Figure 17



(Figure 17). The patient achieved healing of the heel ulcer over the next 6 weeks.

CONCLUSION

Given the wide variety of atherectomy devices available to an interventionist today, there is a question as to how one decides which device is the best in a specific situation. In our experience, Rotablator is more effective in smaller vessels, but it can be used to remodel plaque in the femoral popliteal segment if it has deployment through a guide catheter to bias the wire into the wall or using a diagnostic catheter from above when applying a body floss technique to bias the wire into plaque from above. If you are below the knee and have single-vessel or no-vessel runoff and are concerned about significant embolization, an orbital atherectomy device may not be the best choice. Rotablator, with its front-cutting burr is effective in immediately engaging the lesion and cutting a lumen in tight or occluded lesions. This is particularly useful in densely calcified cases, where newer atherectomy devices that employ plaque excision, and delivery of atheroma at the back of the catheter do not have sufficient power to penetrate through dense atherosclerotic plaque and do not

have a cutting blade of sufficient rebound hardness and shear modulus to effectively engage calcium.

Decision making with the Rotablator System involves a very simple rubric. If the lesion is below the knee, there is single- or no-vessel runoff, and there is concern about significant embolization, the Rotablator System will be the most effective device for drilling a new lumen through which you can advance appropriately sized angioplasty balloons.

The Rotablator System's versatile and unique characteristics, including front-end cutting, low crossing profile, and deliverability, have allowed our practice to successfully treat a significant number of patients with heavily calcified infrapopliteal disease. Our success with the Rotablator System has allowed it to become the device of choice in our practice. ■

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Disclosures: None.

ROTABLATOR™ ROTATIONAL ATHERECTOMY SYSTEM

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

Rotalink Plus INTENDED USE/INDICATIONS FOR USE

The Rotablator Rotational Atherectomy System is intended for percutaneous use in the peripheral vessels in patients with occlusive atherosclerotic disease who are acceptable candidates for endovascular procedures.

RotaWire: INDICATIONS FOR USE/INTENDED USE

These guidewires are intended for use with the Rotablator Rotational Atherectomy System.

Lubricant INDICATIONS FOR USE

Rotaglide lubricant is intended for use with the Rotablator atherectomy system, for the purpose of increasing the lubricity of the system.

CONTRAINDICATIONS AND RESTRICTIONS

Contraindications

1. Occlusions through which a guidewire will not pass.
2. Use in coronary arteries.
3. Long (≥ 20 cm) total occlusions.
4. Angiographic evidence of thrombus prior to treatment with the Rotablator Rotational Atherectomy System. Such patients may be treated with thrombolytics (e.g., Urokinase). When the thrombus has been resolved for two to four weeks, the lesion may be treated with the Rotablator Rotational Atherectomy System.
5. Angiographic evidence of significant dissection at the treatment site. The patient may be treated conservatively for approximately four weeks to permit the dissection to heal before treating the lesion with the Rotablator Rotational Atherectomy System.

Lubricant CONTRAINDICATIONS

Rotaglide™ lubricant is contraindicated in patients with known allergies to the lubricant ingredients: olive oil, egg yolk phospholipids, glycerin, sodium deoxycholate, L-histidine, disodium EDTA, sodium hydroxide, and water.

Restrictions

- Federal (USA) law restricts the use of this system to physicians who are credentialed in peripheral angioplasty and who have attended the Rotablator System Physician Training Program.

WARNINGS

- The risks of Rotational Atherectomy can be reduced if the device and associated accessories are used in the appropriate patient population by a physician who has had adequate training.
- If the Peripheral RotaLink Plus shows evidence of mechanical failure at any time prior to or during the angioplasty procedure, immediately discontinue use of the device and return it to Customer Service for evaluation. Do NOT attempt to use a damaged Peripheral RotaLink Plus; use may result in device malfunction and/or patient injury.

- Never operate the Peripheral RotaLink Plus without saline infusion. Flowing saline is essential for cooling and lubricating the working parts of the advancer. Operation of the advancer without proper saline infusion may result in permanent damage to the advancer.
- Never operate the Peripheral RotaLink Plus with the Rotablator Rotational Atherectomy System in Dynaglide™ mode or operate the guidewire brake defeat button unless you have a firm grip on the guidewire using the wireClip™ Torquer. The wireClip Torquer may be held with the fingers or inserted completely into the docking port after the brake button is depressed. Defeating the brake, or operating the Peripheral RotaLink Plus with the Rotablator Rotational Atherectomy System in Dynaglide mode, without securing the guidewire may result in rotation and entanglement of the guidewire.
- During setup of the Peripheral RotaLink Plus never grip or pull on the flexible shaft.
- The burr at the distal tip of the Peripheral RotaLink Plus is capable of rotating at very high speeds. Do NOT allow parts of the body or clothing to come in contact with the burr. Contact may result in physical injury or entanglement.
- Never advance the rotating burr to the point of contact with the guidewire spring tip. Such contact could result in distal detachment and embolization of the tip.
- If the Peripheral RotaLink Plus stops and the red STALL light on the console illuminates, retract the burr and immediately discontinue treatment. Check the advancer for proper connection to the console. If the connections are correct, use fluoroscopy to analyze the situation. Never force the system when rotational or translational resistance occurs, as vessel perforation may occur.
- Never advance the rotating burr by advancing the sheath. Guidewire buckling may occur and perforation or vascular trauma may result. Always advance the rotating burr by using the advancer knob.
- If resistance is encountered, retract the burr and stop treatment immediately. Use fluoroscopy to analyze the situation. Never force the Peripheral RotaLink Plus when rotational or translational resistance occurs, as vessel perforation, vessel trauma or embolism due to burr detachment or fractured wire may occur and in rare instances may result in surgical intervention and death.
- The use of Rotablator Rotational Atherectomy System for in-stent restenosis might lead to damage of stent components and/or Peripheral RotaLink Plus, which may lead to patient injury.
- Always keep the burr advancing or retracting while it is rotating. Maintaining the burr in one location while it is rotating may lead to excessive tissue removal or damage to the Peripheral RotaLink Plus or entrapment of the Peripheral RotaLink Plus. It is best to advance and retreat the burr no more than 3 cm at a time in a smooth pecking motion, being careful to engage the lesion only minimally when resistance is met. Do not allow the individual burr run time to exceed 30 seconds with total rotational procedure time not to exceed five minutes.

RotaWire WARNINGS

Use extreme caution and careful judgment in patients for whom anticoagulation is not indicated.

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Console WARNINGS

- Never use oxygen as the propellant for the Rotablator Rotational Atherectomy System.
- The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the Rotablator System as replacement parts for internal components, may result in increased emissions or decreased immunity of the Rotablator System.
- This device is not to be used in the presence of flammable anesthetics.
- Do NOT operate the Rotablator Console with gas pressures in excess of 758.4 kPa (110 psi).
- Do not modify or repair.
- Lubricant WARNINGS
- Discard vial if there are particulates in the emulsion or if an oiling-out of emulsion has occurred.

PRECAUTIONS

- Percutaneous rotational angioplasty with the Rotablator Rotational Atherectomy System should only be carried out at medical facilities where prompt treatment can be immediately performed in the event of a potentially injurious or serious complication.
- Appropriate drug therapy including (but not limited to) anti-coagulant and vasodilator therapy must be provided to the patient during all phases of patient care.
- When the Peripheral RotaWire™ Guidewires and/or Peripheral RotaLink Plus are in the body, they should only be manipulated while they are under fluoroscopic observation with radiographic equipment that provides high resolution images.
- Use only normal saline as the infusate. Never inject contrast agent, or any other substance that is not approved as part of the Rotablator Rotational Atherectomy System, into the infusion port or saline infusion bag as this may cause permanent damage to the Peripheral RotaLink Plus.

Console PRECAUTIONS

- User should take precautions when using the console in conjunction with other medical electrical equipment.
- The Rotablator Console needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in Appendix D in the DFU.

ADVERSE EVENTS

Potential adverse reactions which may result from the use of this device include but are not limited to:

- Additional intervention
- Allergic reaction
- Amputation
- Death
- Embolism
- Hematoma/Hemorrhage
- Hemodynamic changes
- Hemoglobinuria
- Infection
- Restenosis
- Stroke
- Slow, no flow, abrupt vessel closure
- Surgery including arterial bypass
- Thrombosis and vessel occlusion

- Vessel trauma (dissection, perforation, pseudoaneurysm, arteriovenous fistula)

There may also be complications associated with distortion, kinks, and fracture of the guidewire and physical deterioration or malfunction of the device, which can lead to patient injury or death.

COYOTE™ BALLOON DILATATION CATHETER

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INTENDED USE/ INDICATIONS FOR USE

The Coyote OTW PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, infra-popliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

CONTRAINDICATIONS

None Known.

WARNINGS

Any use for procedures other than those indicated in these instructions is not recommended.

PRECAUTIONS

- The Coyote OTW PTA Balloon Dilatation Catheter shall only be used by physicians trained in the performance of percutaneous transluminal angioplasty.
- The Coyote OTW PTA Balloon Dilatation Catheter should be used with caution for procedures involving calcified lesions or synthetic vascular grafts due to the abrasive nature of these inflation sites.
- The Coyote OTW PTA Balloon Dilatation Catheters are not intended for injection of contrast medium.
- Precautions to prevent or reduce clotting should be taken when any catheter is used:
- Consider systemic anticoagulation.
- Flush or rinse all products entering the vascular system with sterile isotonic saline or a similar solution prior to use.
- Consult the manufacturers instructions for use when using distal embolic protection devices during angioplasty.

ADVERSE EVENTS

The complications that may result from a balloon dilatation procedure include, but are not limited to:

- Allergic reaction (device, contrast medium and medications)
- Arteriovenous fistula
- Embolization (air, device, plaque, etc.)
- Hematoma
- Hemorrhage, including bleeding at puncture site
- Pseudoaneurysm
- Sepsis/infection
- Thromboembolic episodes
- Vessel injury, e.g. dissection, perforation, rupture
- Vessel occlusion
- Vessel spasm

RUBICON™ SUPPORT CATHETER

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INTENDED USE/INDICATIONS FOR USE

The Rubicon Support Catheter is intended to facilitate placement and support of guidewires and other interventional devices within the peripheral vasculature and to allow for exchange of guidewires, and provide a conduit for the delivery of saline or contrast solutions.

CONTRAINDICATIONS

None Known.

WARNINGS

- The catheter is designed and intended for intravascular use only.
- This catheter is designed and intended for one time use only. Do not re-sterilize and/or reuse.
- This catheter should only be used by physicians qualified to perform percutaneous, vascular interventions
- These catheters are not designed for use in the coronary arteries or the neurovasculature. Any use for procedures other than those indicated in the instructions is not recommended.

PRECAUTIONS

Support Catheters are designed for use by physicians engaged in the practice of a specialized branch of medicine. Use of these devices should be restricted to those specialists trained to perform the procedure. A thorough understanding of the technical principles, clinical applications and risks associated with support catheters is necessary before performing this procedure.

- Precautions to prevent or reduce clotting should be taken when any catheter is used. Use of systemic heparinization should be considered.

ADVERSE EVENTS

Vascular catheterization and/or vascular interventions may result in complications including but not limited to:

- Access site pain
- Allergic reaction (drug, contrast, device & other) and neurological reactions
- Death
- Hemorrhage or hematoma
- Impaired blood flow due to thrombosis, embolism, or vasospasm that could lead to tissue infarction, limb amputation, and other thrombo-embolic organ damage such as renal infarction
- Infection/Sepsis
- Vessel injury (dissection, perforation, trauma & rupture)
- Vasospasm

STERLING™ OVER-THE-WIRE

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INTENDED USE/INDICATIONS FOR USE

The Sterling OTW PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, 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 indicated for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature.

CONTRAINDICATIONS

None Known.

PRECAUTIONS

The Sterling OTW PTA Balloon Dilatation Catheter shall only be used by physicians trained in the performance of percutaneous transluminal angioplasty.

The Sterling OTW PTA Balloon Dilatation Catheter should be used with caution for procedures involving calcified lesions or synthetic vascular grafts due to the abrasive nature of these lesions. Sterling™ OTW PTA Balloon Dilatation Catheters are not intended for injection of contrast medium.

Precautions to prevent or reduce clotting should be taken when any catheter is used:

- Consider systemic heparinization.
- Flush or rinse all products entering the vascular system with sterile isotonic saline or a similar solution prior to use.

ADVERSE EVENTS

The complications that may result from a balloon dilatation procedure include, but are not limited to:

- Allergic reaction to contrast medium
- Arrhythmias
- Arteriovenous fistula
- Cerebrovascular accidents
- Death
- Hematoma
- Hemodynamic instability
- Hemorrhage
- Pseudoaneurysm
- Pyrogenic reaction
- Sepsis/infection
- Thromboembolic episodes
- Vascular thrombosis
- Vessel injury, e.g. dissection, perforation, rupture
- Vessel occlusion
- Vessel spasm

V-18™ CONTROL WIRE GUIDEWIRE WITH ICE COATING

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INTENDED USE/INDICATIONS FOR USE

The V-18 Control Wire guidewire is available in 110, 150, 200 and 300 cm lengths. The wire can be torqued to facilitate the selective placement of diagnostic or therapeutic catheters. This device is intended

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for peripheral use only. A torque device (pin vise) is included with each wire to facilitate directional manipulation of the guidewire. The 110 cm V-18 Control Wire guidewire is intended for general intravascular use including the placement of PTA balloon catheters requiring an 0.018 in guidewire in hemodialysis AV access procedures. The 150, 200 and 300 cm V-18 Control Wire guidewire are intended for general intravascular use.

CONTRAINDICATIONS

Boston Scientific 110 cm Guidewires are not intended for use in the cerebral vasculature.

PRECAUTIONS

This device should be used only by physicians thoroughly trained in percutaneous, intravascular techniques and procedures.

ADVERSE EVENTS

Potential adverse events which may result from the use of the device include but are not limited to:

- Air Embolism/Thromboembolism
- Allergic Reaction
- Amputation
- Arteriovenous (AV) Fistula
- Death
- Embolism
- Hematoma
- Hemorrhage
- Hemoglobinuria
- Infection or Sepsis/Infection
- Myocardial Ischemia and/or Infarction
- Pseudoaneurysm
- Stroke (CVA)/Transient Ischemic Attacks (TIA)
- Thrombus
- Vessel Occlusion
- Vessel Perforation, Dissection, Trauma or Damage
- Vessel Spasm
- Wire Entrapment/Entanglement
- Foreign Body/Wire Fracture

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