Rotarex™

Rotational Excisional Atherectomy System

Rotarex™ Catheter Set

Size	Length (cm)	Product Codes
6F	110	☐ 80236
	135	☐ 80237
8F	85	☐ 80238
	110	☐ 80239

Spare Rotarex™ Guidewires (5-Pack)

Diameter	Length (cm)	Tip	Flexible Tip	Product Codes
0.018"	220	Angled	40 mm	☐ 80320
	270	Angled	40 mm	☐ 80321
	320	Angled	40 mm	☐ 80322

Rotarex™ Drive System

Description	Product Codes
Drive System	☐ 80400

❯ Rotarex™ Catheter Set includes catheter, guidewire, sterile drape and collecting bag

REFINED ATHERECTOMY
BUILT TO REMOVE
ATHERECTOMY + THROMBECTOMY

Rotarex™ Rotational Excisional Atherectomy System

Indication For Use: The Rotarex™ Atherectomy System is intended for use as an atherectomy device and to break up and remove thrombus from native peripheral arteries or peripheral arteries fitted with stents, stent grafts or native or artificial bypasses.

Contraindications: · In patients not suitable for atherectomy/thrombectomy · In the cardiopulmonary, coronary, carotid, cerebral and renal vasculature · In vessels that are undersized for the device used · In the venous vasculature

Warnings: Do not use in anatomical locations with persistent vasospasm · The Rotarex™ family of catheters may only be used with the BD supplied guidewire with which they are packaged · The catheter must always be guided via the supplied guidewire, which has been correctly positioned according to the instructions for use. Do not use the catheter without the supplied guidewire or over the supplied guidewire which is incorrectly placed · If the supplied guidewire is in a subintimal position of any length, reposition and ensure it is intraluminal before proceeding · Do not use the catheter if the supplied guidewire has become threaded or entangled in the wire mesh of a stent, stent graft or the lining of a stent graft · Position the flexible tip of the supplied guidewire as far distally as possible from the vessel occlusion being treated to avoid the tip being aspirated into the rotating helix. Recommended distance is at least 10 cm. Operators should take care that manipulations of the catheter do not alter the desired position of the supplied guidewire · Do not use this device at or near locations with pre-existing damage to the vessel wall from prior surgery, aneurysms, or other disease · Remove catheter and supplied guidewire from patient before employing magnetic resonance imaging (MRI) or using a defibrillator · Do not use Rotarex™ Atherectomy Catheters when product damage is evident, whose packaging is damaged, or where the sterilization expiration date has passed · This device is intended for use only by suitably qualified medical personnel experienced in the diagnosis and treatment of peripheral vascular disease by percutaneous methods · This device may only be used in conjunction with the Drive System

· This device is supplied sterile for single-use only. Do not reprocess or resterilize. Resterilization or reconditioning may severely impair the function of the device · Risk of distal embolization is greatly increased if the operator attempts to advance the catheter faster than the recommendations in these instructions, especially near the distal end of the occlusion · Failure to ensure sufficient blood flow to the catheter head could result in vessel collapse · Monitor the blood flow to the collecting bag continuously throughout the procedure · Do not operate near fractured areas of broken stents or stent grafts. If a protruding stent strut penetrates into the side window of the catheter head, the stent, stent graft or vessel may become severely damaged, destroyed and/or dislodged, or the catheter head may become entrapped in the stent or stent graft in such a manner that the catheter and the stent or stent graft must be surgically recovered · This device should only be used under adequate visual monitoring with suitable radiographic techniques

The helix rotates at a high rate of speed and may be at risk of failure when exposed to certain conditions. Improper device use may cause the helix to fracture or break, requiring retrieval of a broken catheter or device fragment. A helix facture or break could cause vessel injury and lead to severe bleeding or death. It is essential to follow all instructions and directions for use to reduce the risk of a helix fracture or break.

· Use a kink resistant, suitably reinforced sheath of the same size as the Rotarex™ Atherectomy Catheter, or 1 French size bigger. When choosing a contralateral approach this may also serve to facilitate a smooth transition across the aortic bifurcation. · Do not use the device across a vessel bifurcation or curve that results in a curvature of the catheter shaft of <4 cm in diameter. Consider the use of ipsilateral access if contralateral access is expected to result in a catheter bend less than 4 cm in diameter. · Maintain adequate blood flow through the catheter to reduce the risk of catheter overheating or blockage. Adequacy of blood flow can be assessed by observing continuous drainage into the collecting bag and listening for changes in the audible pitch of the motor. · Maintain constant catheter movement to reduce fatigue stress on the inner helix in one location. Perform a smooth back and forth motion within the target lesion. Use a 10 mm forward motion (equivalent to one catheter head) for softer materials and 1 mm for denser lesions. · Do not use the device in calcified vessel segments that exhibit radiopacities on both sides of the arterial wall and extend beyond 10 mm in length prior to contrast injection or digital subtraction angiography. · Monitor the catheter closely for resistance to movement. Audible control unit alarms (i.e., intermittent beeping) or changes in tactile feel of the catheter, pitch sound of the motor, or LED bar illumination on the control unit (where the green light is no longer illuminated, leaving only the yellow/orange light illuminated) indicate the need to reduce catheter advancement from increments of 10 mm to 1 mm, stop, or flush the catheter.

Precautions: · This device does not contain any parts that can be maintained or serviced by the end-user. Do not repair or change the configuration of the device · Use of the device through a kinked or damaged introducer or where the catheter itself has become kinked or bent, may cause erratic function and/or device failure · Catheters must not be allowed to operate "dry" and must be primed and flushed using heparinized saline before and during use per the instructions in this IFU. Throughout catheter use, always ensure there is a sufficient blood flow to the catheter head. Allowing the catheter to operate without heparinized saline solution priming and flushing or without adequate amounts of aspirated blood, will cause the device to operate erratically and/or cease functioning · Failure to manipulate the catheter slowly in a back and forth motion as described in these instructions may result in fracture of the helix and/or supplied guidewire · Insufficient blood flow through the catheter may result in intra-catheter clotting, slow or absent therapeutic function, fracture of the helix and/or supplied guidewire, and/or overheating of the catheter · The guidewire adaptor must be in the working position (pulled back) when the motor is active · When active, the handle of the Rotarex™ Catheter and the portion of the catheter outside the patient's body must be kept at he same height as the introducer sheath and straight at all times with the outlet tube to the collecting bag hanging vertically below the motor in a straight line. Failure to position the catheter and outlet tube in this manner may result in catheter blockage, helix fracture and/or supplied guidewire fracture · If the supplied guidewire begins to rotate with the helix, which may occur if the helix and supplied guidewire become bonded with fibrin, the procedure must be immediately stopped; the catheter thoroughly flushed and the supplied guidewire changed

Potential Adverse Events: Potential adverse events include, but are not limited to: · Embolization, especially distal embolization · Pulmonary embolisms of all degrees of severity · Thrombosis · Re-occlusion · Vessel wall injury · Vessel dissection / perforation / rupture · Perforation as a result of mural calcium being torn out of the vessel wall · Arteriovenous fistula / pseudo-aneurysm · Hematoma, bleeding, hemorrhage · Organ perforation · Implants such as stents / stent grafts / bypass grafts getting damaged, caught or dislodged · Disruption of the catheter: debris remaining in the body · Allergic reactions, including allergic reactions to device components · Infections or necrosis at the puncture site · Catheter-induced sepsis · Death

Please consult product labels and instructions for use for indications, contraindications, hazards, warnings, and precautions. BD, the BD Logo and Rotarex are trademarks of Becton, Dickinson and Company or its affiliates. BD-39385v6

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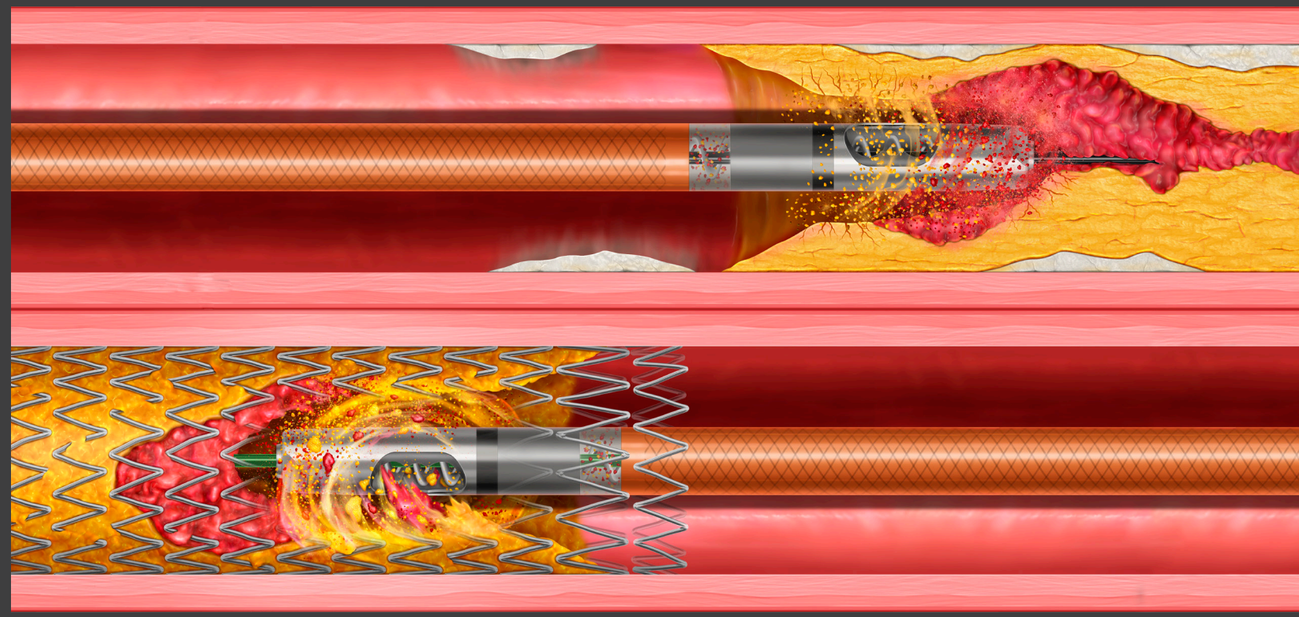

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BD, Tempe, AZ, USA, 1 800 321 4254

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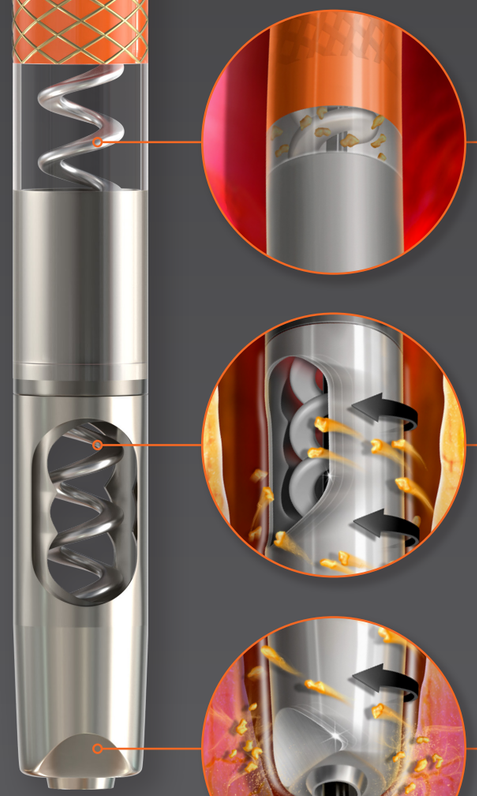
BUILT TO REMOVE
PLAQUE & THROMBUS

The Rotarex™ Atherectomy System is designed to efficiently remove both plaque and thrombus by utilizing three distinct mechanisms of action to treat PAD lesions including in-stent restenosis.

INDICATED FOR USE IN THE PERIPHERAL ARTERIES FOR:

- ☑ Native Lesions
- ☑ In-Stent Restenosis
- ☑ Stent Grafts
- ☑ Native or Artificial Bypass
- ☑ Atherectomy
- ☑ Thrombectomy



CONTINUOUS ACTIVE ASPIRATION

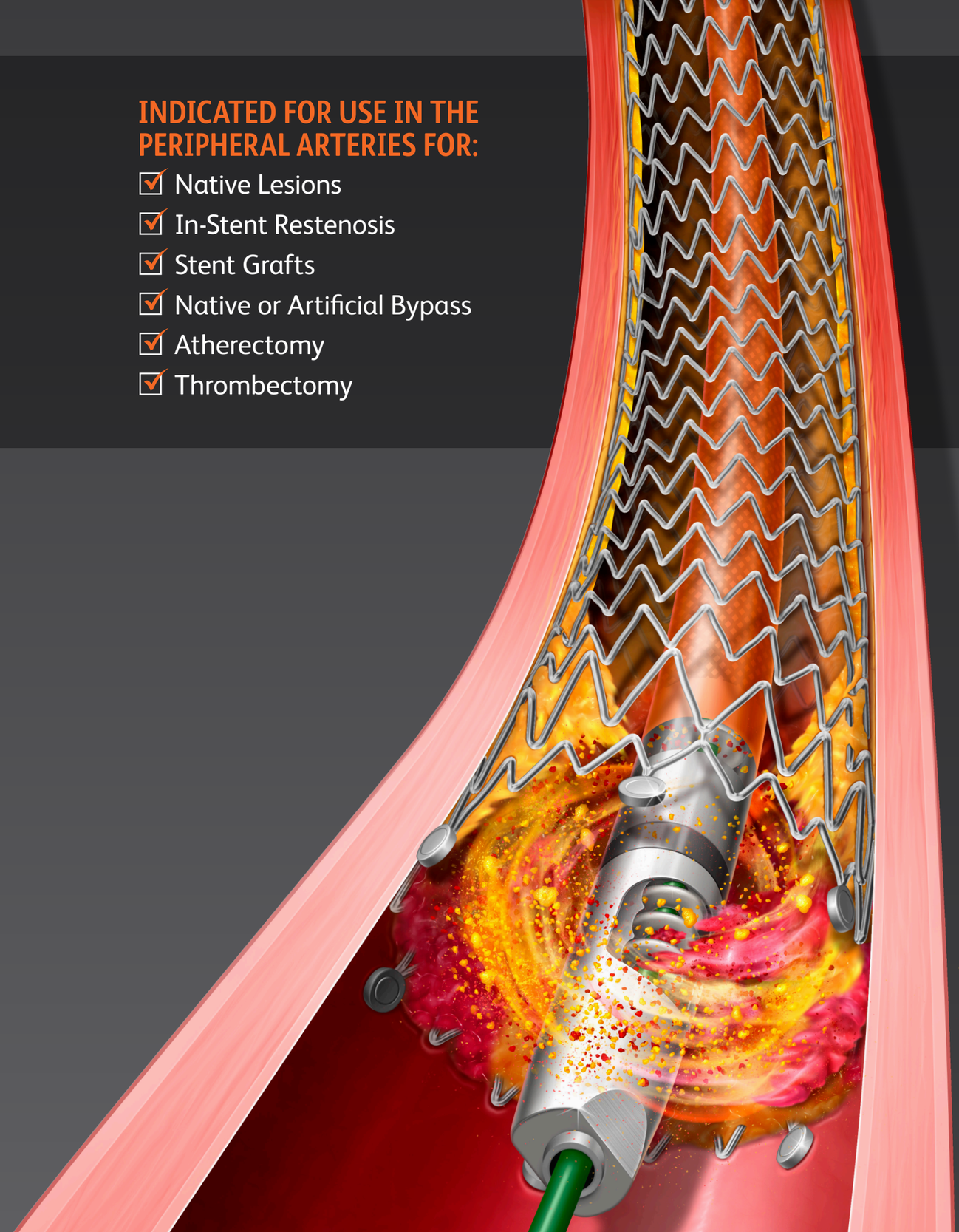
- Internal helix creates negative pressure at the tip to actively aspirate and transport material away

ROTATING ABRADING VORTEX

- Vortex creates additional luminal gain around the cylinder
- Large side windows further break down and efficiently remove detached material

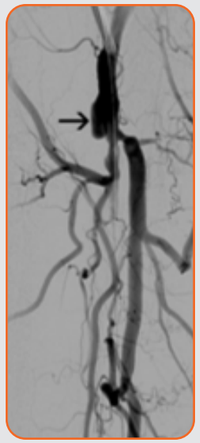
MODIFYING BEVELED TIP

- Catheter head and helix rotate at approximately 40,000 and 60,000 RPMs, depending on catheter size

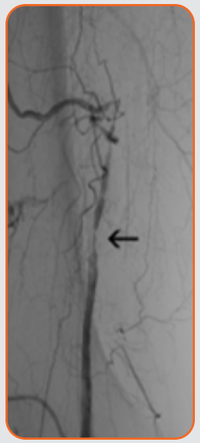


REAL WORLD **CLINICAL EXPERIENCE**

Bypass Case: 61-year-old male presented with subacute ischemia of the left lower limb, Rutherford 4, proximal, prosthetic bypass thrombosis (antegrade approach)
Dr. Bulvas, MD, PhD, Associate Professor Miroslav

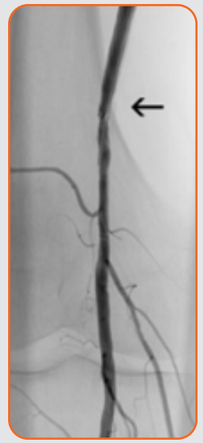


Occluded prosthetic bypass insertion, stenosis of deep femoral artery (DFA)

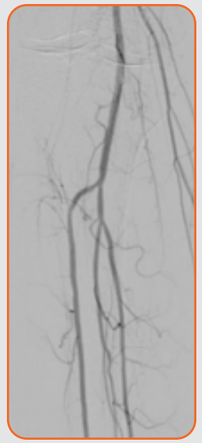


PA filled via collaterals: distal anastomosis

Distal anastomosis after bypass debulking with Rotarex™ Atherectomy Device

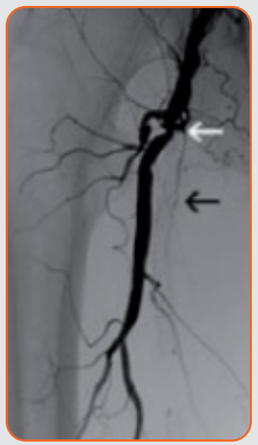


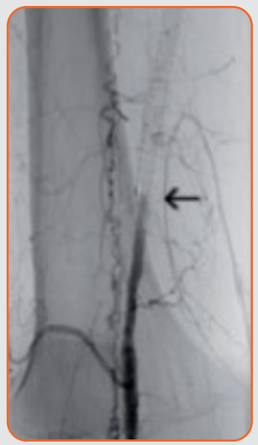
Distal anastomosis after PTA and stenting



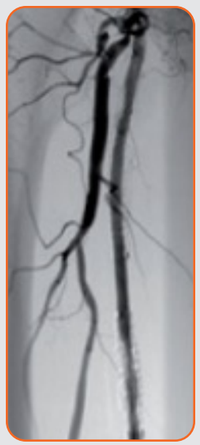
Tibial vessels

In-Stent Restenosis Case: 59-year-old male presented with acute ischemia of the right lower limb, Rutherford IIb
Dr. Bulvas, MD, PhD, Associate Professor Miroslav

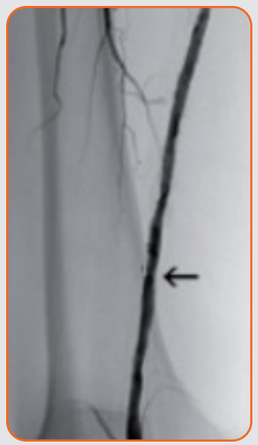




Before treatment the SFA is occluded at its origin (white arrow), proximal margin of stented area is depicted by black arrow. The popliteal artery is filled via collaterals.



After treatment with Rotarex™ Atherectomy Device Alone



After adjunctive PTA

The Rotarex™ Atherectomy System has been studied in over 2,100 patients.

A meta-analysis of 8 clinical studies comprising data obtained from 2,107 patients studied from 2002 to 2015 was performed to*:

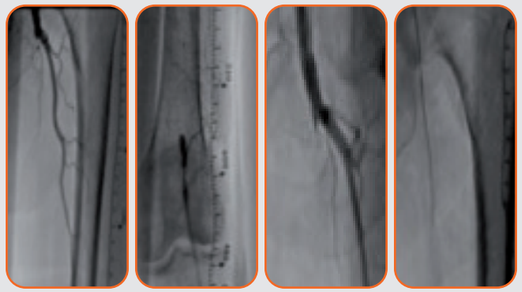
- Establish Rotarex™ Atherectomy System clinical performance
- Provide a quantitative review and synthesis of the results of related but independent studies of the Rotarex™ Atherectomy Device

Measure/Outcomes	Mean (95% CI)
Age	68.1 (66.4, 69.7)
Gender (% Male)	65.3% (60.6%, 70.0%)
Rotarex™ Device Treatment Time (minutes)	3.0 (1.3, 4.7)
Lesion Length (mm)	153.96 (115.24, 192.69)
Technical Success	95.8% (94.3%, 97.3%)
Clinical Success	79.9% (75.2%, 84.5%)
TLR at 6 Months	7.8% (1.0%, 14.5%)
TLR at 12 Months	11.3% (7.4%, 15.3%)
Restenosis at 6 Months	16.9% (0.0%, 35.3%)
Restenosis at 12 Months	35.5% (19.6%, 51.4%)

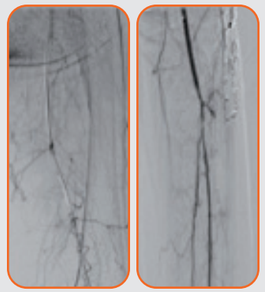
Measure/Outcomes	Mean (95% CI)
ABI at Baseline	0.33 (0.18, 0.47)
ABI at 6 Months	0.83 (0.78, 0.88)
ABI at 12 Months	0.77 (0.71, 0.82)
Rutherford Score at Baseline	3.54 (3.42. 3.67)
Rutherford Score at 6 Months	1.51 (1.03, 2.00)
Rutherford Score at 12 Months	2.13 (1.83, 2.42)
Procedure-Related Dissection	5.9% (3.3%, 8.6%)
Procedure-Related Embolization	7.5% (4.7%, 10.4%)
Procedure-Related Perforation	2.2% (0.9%, 3.4%)
Procedure-Related Pseudo-Aneurysm	1.5% (0.6%, 2.4%)
Procedure-Related Abrupt Reocclusion	2.4% (1.0%, 3.7%)

* The statistical treatment of the data summarized in the table above endpoints with an adequate number of data points (>2). SAS v9.3 (SAS Institute, Cary, NC) was used to pool data and calculate all estimates. For each clinical outcome, a random effects model was executed to calculate pooled estimates per group, as well as the corresponding confidence

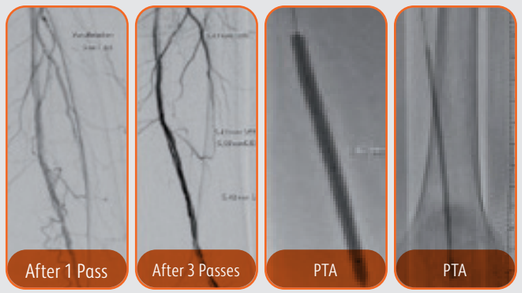
CTO Left SFA: 64-year-old male patient presented with left-sided CLI
Dr. Bruno Freitas, MD, Prof. Santa Casa de Maceió, Federal University of Alagoas



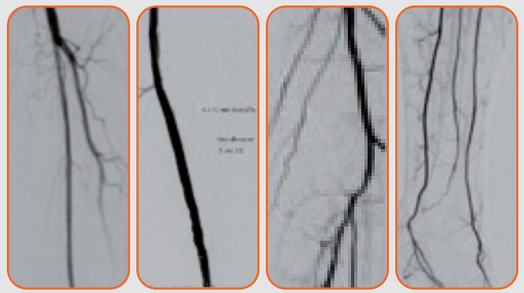
Before treatment. Flush occlusion of left SFA to PII segment. Crossed intraluminally with guidewire.



Extensive collaterals of SFA reconstituting at PII segment, with 2 vessel run-off BTK.



Angiogram after 1 and 3 passes with Rotarex™ Atherectomy Catheter. PTA follows Rotarex™ Atherectomy treatment

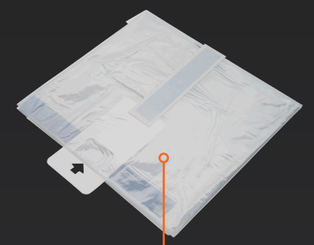


Final angiogram showing restored flow in SFA and 3 vessel run-off BTK

SMALL FOOTPRINT
SIMPLE TO SET UP

- No warm-up, infusion, or repeated catheter clean-out required
- Plug-and-play capital component

Catheter Set Includes:
- Catheter
- Guidewire
- Sterile Drape
- Collecting Bag



STERILE DRAPE

COLLECTING BAG

- High volume collecting bag allows for uninterrupted removal of occluding material

SWITCH

- Operated by hand or optional-use foot switch to facilitate single- or multiple-operator scenarios
- Magnetic coupling facilitates ease of use while in the sterile environment

ERGONOMIC HANDLE

- Easy to use handle designed for single operator control
- Disposable catheter simply clips to reusable portion of the handle
- Included with catheter set

CATHETER

- Designed to perform in a variety of lesions, including complex, mixed morphology occlusions
- No defined limitation on treatable lesion length

DRIVE SYSTEM

- Small, portable design
- Easy set-up; plug-in and switch on
- System is auto-aspirating, without the need for a separate pump

GUIDEWIRE

- Nitinol core shaft with PTFE coating for catheter support
- Gold-plated tungsten coil to enhance visualization under fluoroscopy

OPTIONAL FOOT SWITCH

- Operated by foot switch or by handle to facilitate single- or multiple-operator scenarios