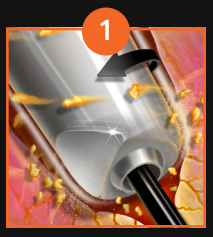
Refining Atherectomy



Modifying beveled tip

Rotating abrading vortex

Continuous active aspiration

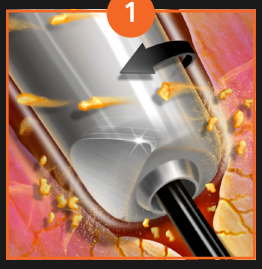
Rotarex™

Rotational Excisional Atherectomy System

BD

Refining Atherectomy & Aspiration Together

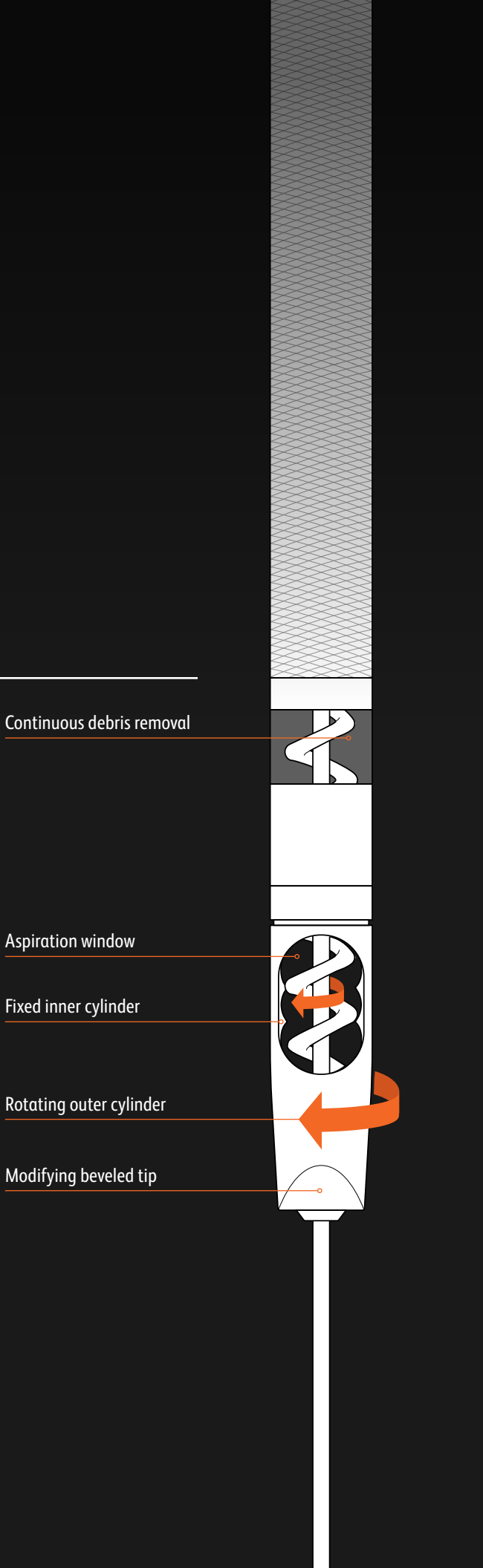
The Rotarex™ Rotational Excisional Atherectomy System is Swiss-made precision that synchronizes three distinct mechanisms of action, negotiating even complex lesions without external blades, and all with a small equipment footprint that sets up in minutes.



Rotating atraumatic catheter head with blunt facets modifies and detaches mixed morphology lesions.

Additional luminal gain is achieved by a vortex created around the rotating cylinder. Large side windows further break down and efficiently remove detached material.

Rotating helix creates continuous negative pressure at tip; actively aspirating and transporting material away.



REAL WORLD CLINICAL RESULTS

Atherectomy With Thrombectomy of Femoropopliteal Occlusions with Rotarex S: The Leipzig Experience Presented by Bruno Freitas, MD at Charing Cross 2019

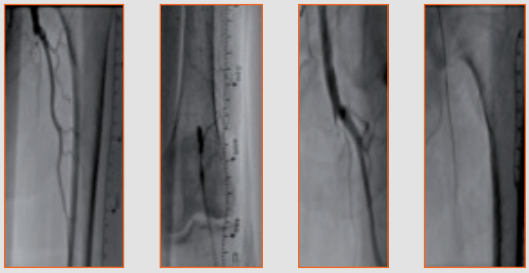
Retrospective review in a real-world scenario with consecutive patient enrollment between Jan. 2011 and Nov. 2013.[1]

Total Procedures Studied: 658

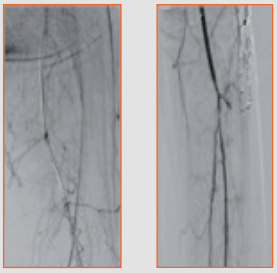
Revascularization at 12-months	**90.1%**	Freedom from Target Lesion Revascularization		
Clinical Success at 12-months	**78.7%**	Clinical Success (% of N=658 patients with improvement of ≥1 Rutherford Class)		
Challenging Lesions	**51.2%**	Calcified Lesions[2]	**14.8 cm**	Average Lesion Length
	60.3%	Rutherford 4-6 at Admission	**56.0%**	Chronic Lesions

CTO Left SFA Dr. Bruno Freitas, MD, Prof. Santa Casa de Maceió, Federal University of Alagoas[1]

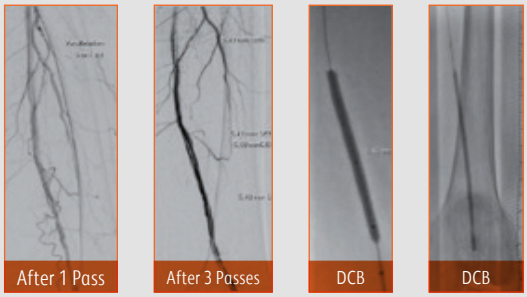
64-year-old male patient presented with left-sided CLI. Over the preceding four months the patient experienced left-sided rest pain and despite receiving best medical treatment, developed a dry, non-healing ulcer of the toe. Puncture of the right groin and a cross-over approach, demonstrated a very long, 31 cm, TASC D, femoropopliteal CTO on angiogram. The SFA occlusion was recanalized with a wire intraluminally, followed by 3 passes of a 6F Rotarex S™ Atherectomy Catheter, after which 3 DCBs resulted in a completely restored flow. The patient remained asymptomatic after 18 months.



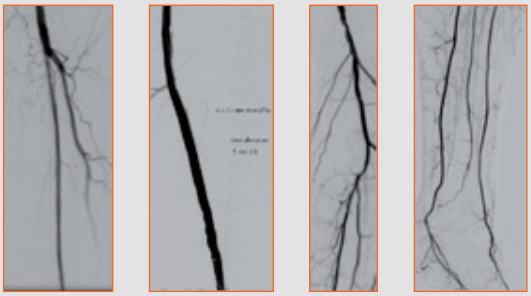
Before treatment. Flush occlusion of left SFA to PII segment. Crossed intraluminally with guidewire.



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



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



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

[1] The clinical experiences presented herein are for informational and educational purposes only. The results presented may not be predictive for all studies and patients. Results may vary depending on a variety of experimental and clinical parameters, as well as patient specific attributes. The treatments described in this presentation represent those of the presenting physician. Please consult product labeling for appropriate use. 3.2% distal embolization rate at 12 months, distal embolic protection used in 6.2% of cases

[2] The use of Rotarex™ System Catheters are contraindicated in vessels in which the target lesion is heavily calcified.

SIMPLE TO SET-UP & USE

- Small Footprint
- Simple Setup
- No Warm-up, Infusion, or Repeated Catheter Clean-Out Required

INTELLIGENTLY DESIGNED

- Excisional Atherectomy without Exposed Blades
- Continuous Aspiration of both Plaque and Acute to Chronic Thrombus
- Dual Indicated for Peripheral Arterial Atherectomy and Thrombectomy

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

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
- Hydrophilically-coated with a flexible, angled tip to enable lesion crossing
- Gold-plated tungsten coil to enhance visualization under fluoroscopy

Collecting bag

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

* Optional foot-switch depicted on following page (included with Drive System)

Rotarex™

Rotational Excisional Atherectomy System

Rotarex™ Catheter Set

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

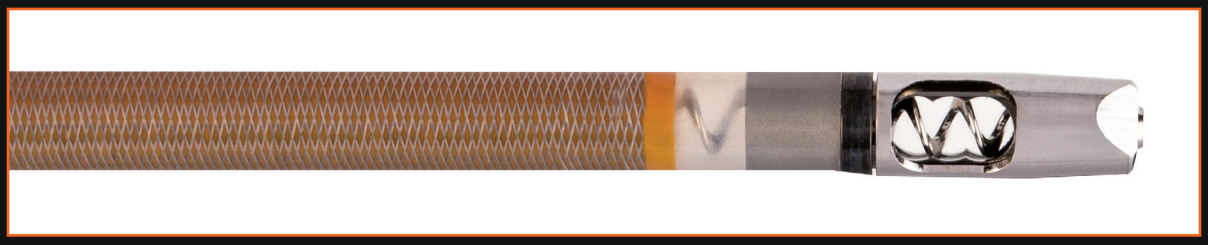
Set includes catheter, guidewire, sterile drape, and collecting bag

Spare Rotarex™ Guidewires (5-Pack)

Diameter	Length (cm)	Tip	Flexible Tip	Hydrophilic Coating	Product Codes
0.018"	220	Angled	40 mm	9.5 cm	☐ 80320
	270	Angled	40 mm	9.5 cm	☐ 80321
	320	Angled	40 mm	9.5 cm	☐ 80322

Rotarex™ Drive System

Description	Product Codes
Drive System	☐ 80300



Rotarex™ Rotational Excisional Atherectomy System

Safety and Risk Information

The Straub Endovascular System is herein referred to as the BD Rotarex™ Rotational Excisional Atherectomy System

Indication For Use

When operated with a Rotarex™ single use catheter, the Straub Endovascular System is intended for use as an atherectomy device and to break up and remove thrombus from upper and lower extremity peripheral arteries. It is not intended for use in coronary, carotid, pulmonary, iliac or renal vasculature.

Contraindications

Use of the Rotarex™ family of catheters is contraindicated in the following situations and locations: · In the cardiopulmonary, coronary, cerebral, iliac and renal vasculature · In the venous vasculature · In instances of persistent vasospasm · In patients not suitable for atherectomy/ thrombectomy · In patients with known or suspected allergies to any component of the Straub Endovascular System · In patients with hemodynamic instability, shock or severe coagulatory disorders · In patients where it is impossible to achieve sufficient anticoagulation and platelet aggregation inhibition · In areas of known or suspected infection, especially at the puncture site or target vessel segment · In vessels which are oversized or undersized for the particular Rotarex™ catheter used · In stents, stent grafts or bypass grafts · Without the use of a Straub provided guidewire · When the Straub provided guidewire cannot completely cross the target lesion · Where the Straub provided guidewire is in a subintimal position of any length · Where the Straub provided guidewire has become threaded or entangled in the wire mesh of a stent, stent graft or the lining of a stent graft · Where the target lesion is located in a region of marked vessel tortuosity (has a radius of curvature ≤2 cm) or is heavily calcified · Where pre-existing damage is present in the vessel wall at or near the target lesion from prior surgery, aneurysms or other disease · During MRI procedures or where electrical current may be passed to an undesired location via the catheter, e.g., during electrocautery, electrosurgery or defibrillation. The Rotarex™ catheter and guidewire must be entirely removed before these therapies are administered, even in an emergency situation · Where the recommended separation distances from Radio Frequency and Electro-Magnetic Interference (EMI) sources cannot be maintained (Reference the manual for the Drive System) · Where any component of the Straub Rotarex™ Endovascular System has sustained damage, including any breech of the sterile barrier

Warnings

· Rotarex™ catheters and the Drive System are intended for use only by suitably qualified medical personnel experienced in the diagnosis and treatment of peripheral vascular disease by percutaneous methods · The Rotarex™ family of catheters may only be used in conjunction with the Drive System · The Rotarex™ family of catheters may only be used with the Straub provided guidewire with which they are packaged · Rotarex™ catheters are supplied sterile for single-use only. Do not reprocess or resterilize. Resterilization or reconditioning may severely impair the function of the product · Do not use Rotarex™ catheters whose packaging is damaged or whose sterilization expiration date has passed · Position the flexible tip of the 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 >10 cm (4 in). Operators should take care that manipulations of the catheter do not alter the desired position of the guidewire · Risk of distal embolization is greatly increased if the operator attempts to advance the catheter faster than the recommendations in the instructions for use, 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 the Rotarex™ catheter 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 · Rotarex™ catheters should only be used under adequate visual monitoring with suitable radiographic techniques

Cautions

· Rotarex™ catheters do not contain any parts that can be maintained or serviced by the end-user. Do not repair or change the configuration of the product · Use of the Rotarex™ catheter through a kinked or damaged introducer or where the catheter itself has become kinked or bent, may cause erratic function and or device failure · Rotarex™ 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 the 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 the instructions for use may result in fracture of the helix and/or guidewire · Insufficient blood flow through the catheter may result in intra-catheter clotting, slow or absent therapeutic function, fracture of the helix and/or 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 the 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 guidewire fracture

Potential Adverse Effects

· Embolization, especially distal embolization · Pulmonary embolisms of all degrees of severity · Thrombosis, especially recurrent 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 · Infections or necrosis at the puncture site · Catheter-induced sepsis · Death

Please consult package insert for more detailed safety information and instructions for use.

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