Refining Atherectomy

Rotarex™
Rotational Excisional Atherectomy System
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.

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

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

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

Continuous debris removal
Aspiration window
Fixed inner cylinder
Rotating outer cylinder
Modifying beveled tip
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. Total Procedures Studied: 658

<table>
<thead>
<tr>
<th>Revascularization at 12-months</th>
<th>90.1% Freedom from Target Lesion Revascularization</th>
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</thead>
<tbody>
<tr>
<td>Clinical Success at 12-months</td>
<td>78.7% Clinical Success (% of N=658 patients with improvement of ≥1 Rutherford Class)</td>
</tr>
</tbody>
</table>
| Challenging Lesions           | 51.2% Calcified Lesions
|                               | 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

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.

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

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

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

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**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

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*Optional foot-switch depicted on following page (included with Drive System)*
Rotarex™ Catheter Set

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

Rotarex™ Drive System

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Spare Rotarex™ Guidewires (5-Pack)

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<th>Tip</th>
<th>Flexible Tip</th>
<th>Hydrophilic Coating</th>
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