



# Overview of the Rotarex Rotational Atherectomy System

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# Disclosure

Speaker name: Miguel Montero-Baker, MD

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I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)
  
- I do not have any potential conflict of interest

# Disclaimer

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The opinions and clinical experiences presented herein are for informational purposes only. The results from these case studies may not be predictive for all patients. Individual results may vary depending on a variety of patient specific attributes. The physician has been compensated by BD.

# Rotarex™

## Rotational Excisional Atherectomy System

	Rotarex™ 6F Device	Rotarex™ 8F Device
Vessel diameters	3 - 5 mm	5 - 8 mm
Catheter type	0.018" / OTW	0.018" / OTW
Usable length	110 cm, 135 cm	85 cm, 110 cm
Sheath compatibility	6F	8F
Max. rotation speed	60,000 rpm	40,000 rpm
Max. aspiration rate	45 ml/min	75 ml/min
Catheter external diameter	2 mm	2.7 mm



# Atherectomy Mechanism Comparison

- Atherectomy devices must be versatile in order to treat multiple plaque morphologies
- Rotarex™ Rotational Excisional Atherectomy System combines the grinding of denser materials with powerful aspiration to address thrombus and emboli

	Rotarex™	Orbital	Directional	Laser
Atherectomy and Thrombectomy	+	-	-	-
Active aspiration	+	-	-	-
Front debulking	+	-	-	+
Occlusions	+	-	+	+
Thrombus	+	-	-	+
Calcium <sup>1</sup>	+	+	+	-

<sup>1</sup>The use of Rotarex™ System Catheters are contraindicated in vessels in which the target lesion is heavily calcified.

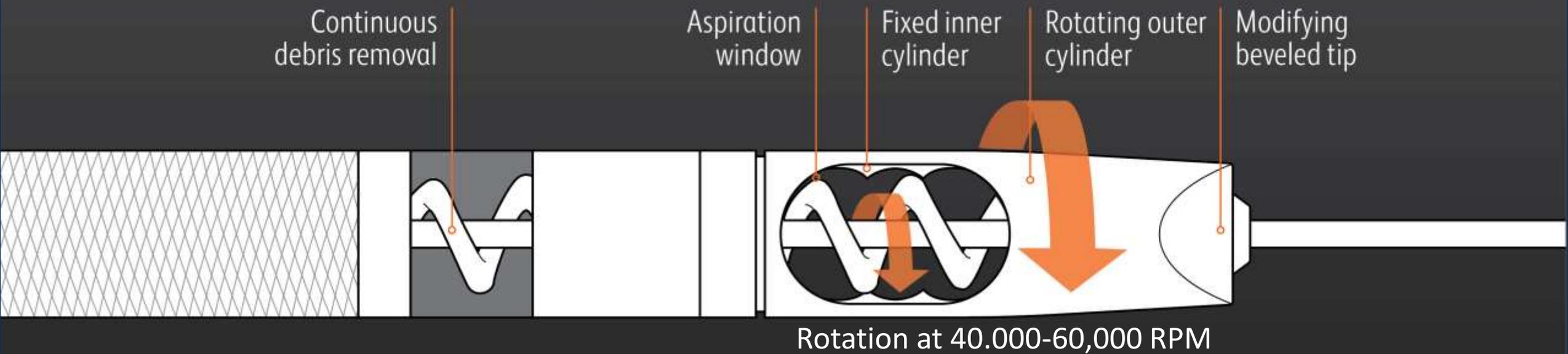
# Rotarex™

## Rotational Excisional Atherectomy System

- Designed for multiple plaque morphologies
- Dual indicated for peripheral arterial atherectomy and thrombectomy
- Continuous active aspiration through large side windows
- Atraumatic design
- Simple to setup and use



# Catheter Design

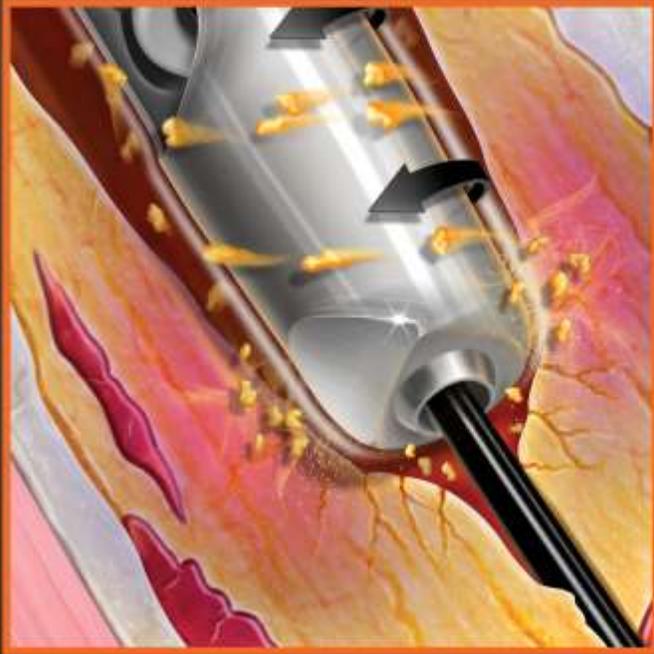


**Rotarex™**

Rotational Excisional Atherectomy System

# Mechanism of Action

Rotarex™  
Rotational Excisional Atherectomy System



Modifying Beveled Tip



Rotating Abrading Vortex



Continuous Active Aspiration

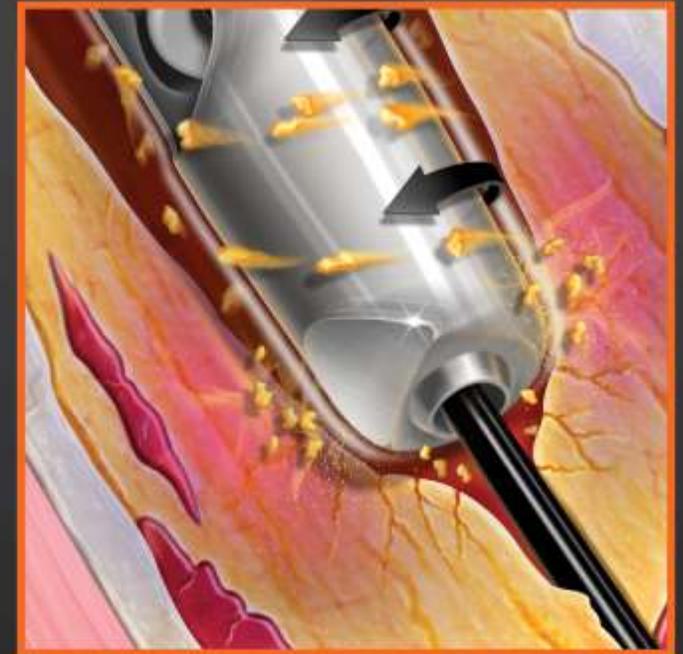
# Mechanism of Action

Rotarex™

Rotational Excisional Atherectomy System

## Modifying Bevel Tip

- Blunt atraumatic facets modify and detach diseased material
- Addresses mixed morphology lesions



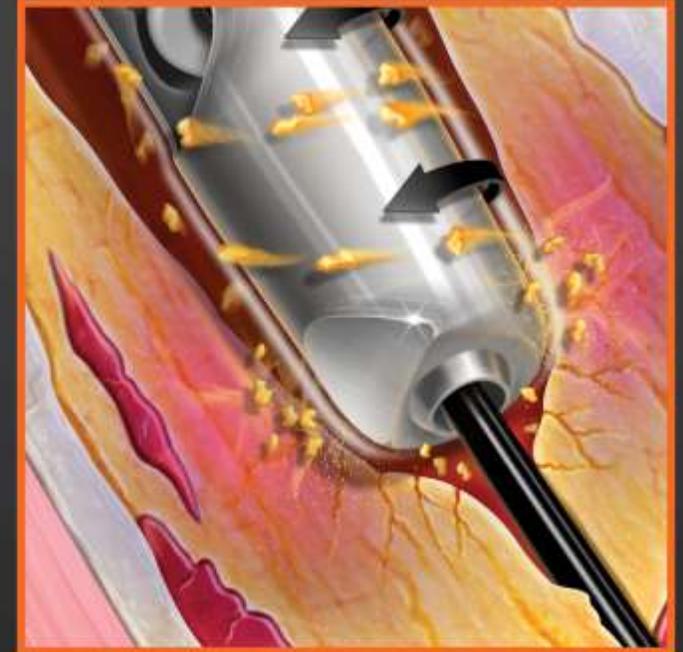
# Mechanism of Action

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Rotational Excisional Atherectomy System

## Rotating Abrading Vortex

- **External:** Vortex erodes occlusive material to increase luminal gain
- **Internal:** Material is further broken down by cutting mechanism in side-windows



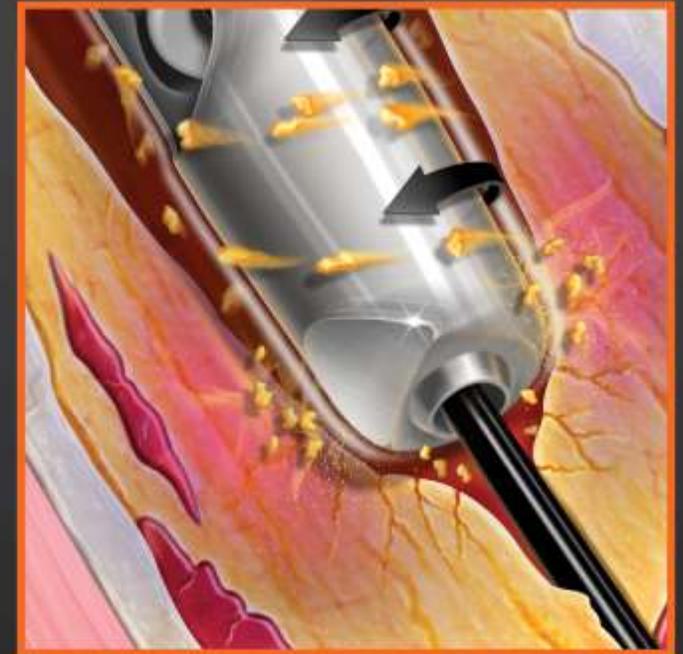
# Mechanism of Action

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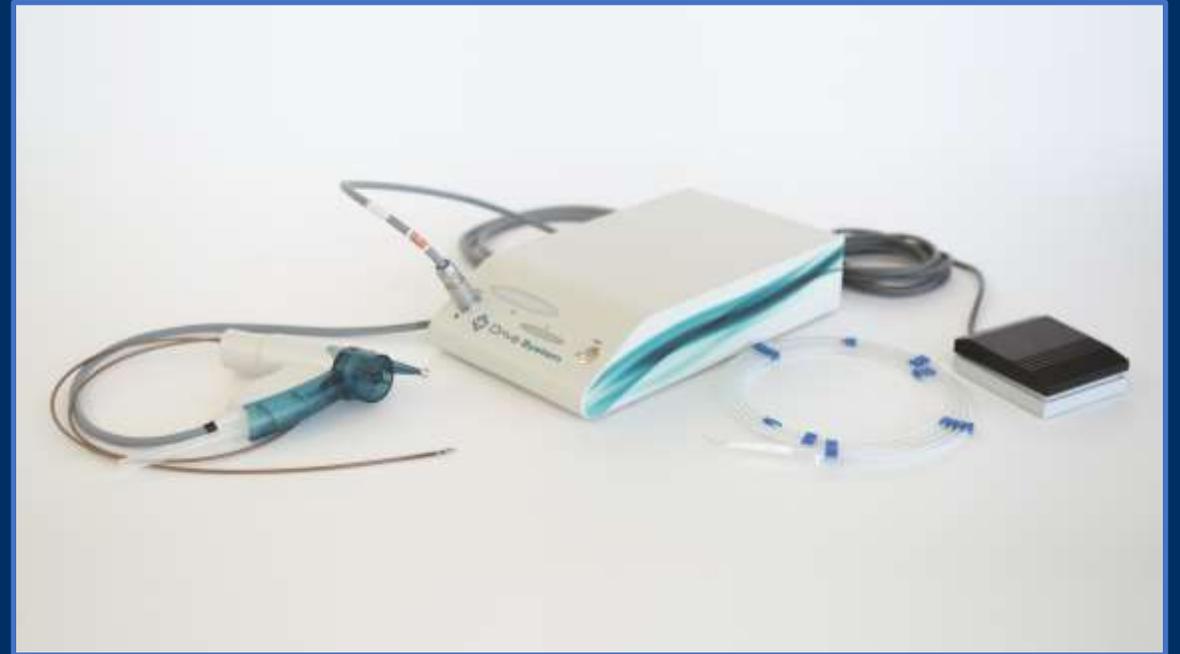
## Continuous Active Aspiration

- Rotating helix creates powerful negative pressure at tip through side windows



# Simple Set-up and Use

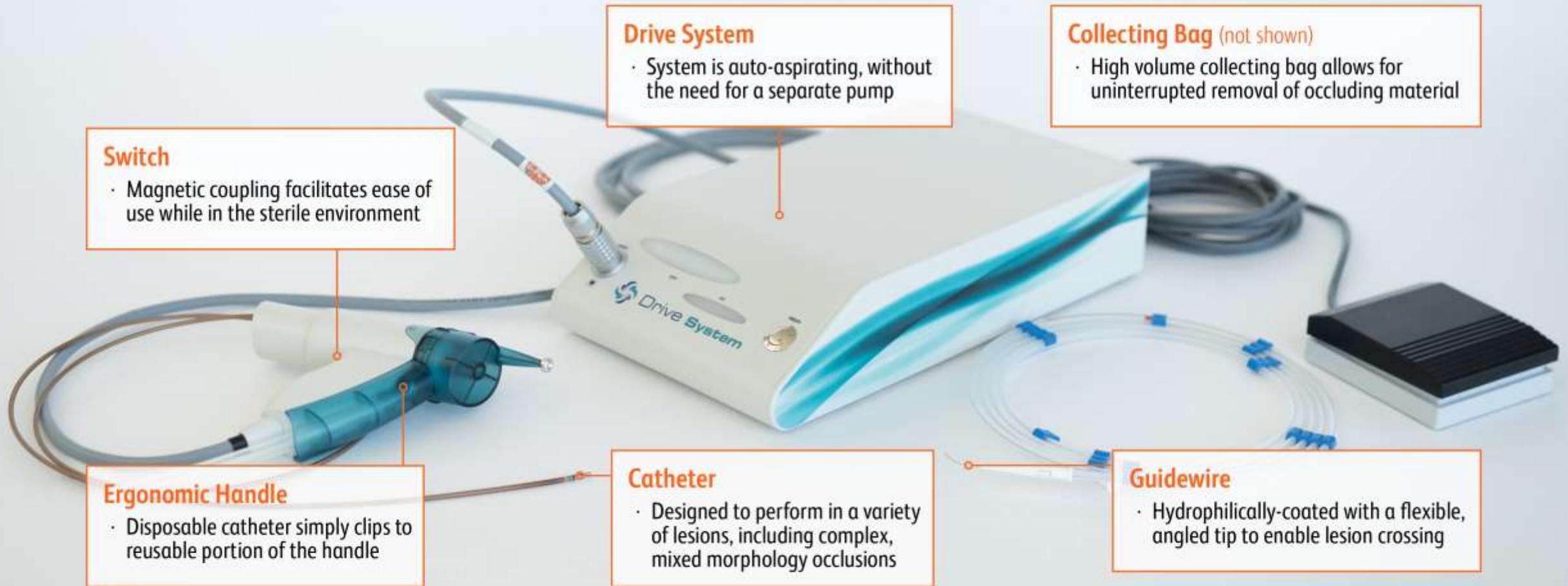
- Small footprint
- Sterile catheter simply snaps to motor handle
- No routine saline or lubricant requirement
- No warm-up, infusion, or repeated catheter clean-out required



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Rotational Excisional Atherectomy System

# System Components



## Drive System

- System is auto-aspirating, without the need for a separate pump

## Collecting Bag (not shown)

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

## Switch

- Magnetic coupling facilitates ease of use while in the sterile environment

## Ergonomic Handle

- Disposable catheter simply clips to reusable portion of the handle

## Catheter

- Designed to perform in a variety of lesions, including complex, mixed morphology occlusions

## Guidewire

- Hydrophilically-coated with a flexible, angled tip to enable lesion crossing

# Clinical Benefits

## Wide Range of Clinical Applications

- Upper and lower extremity peripheral arteries
- 3-8 mm arteries
- Acute, subacute, **and** chronic lesions
- Dual indication: Removes atheroma **and** thrombus

## Intelligent Design

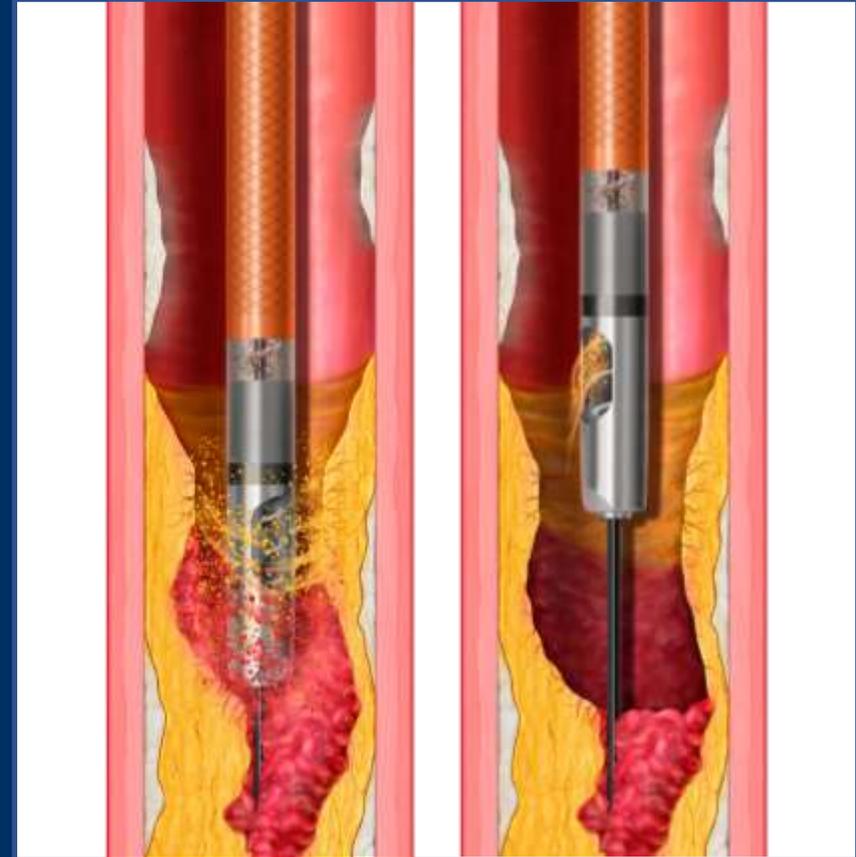
- Unique, magnetic slip-clutch ensures instant disengagement of the drive should obstruction occur
- Abrading vortex effect enables additional luminal gain without external blades



# Clinical Benefits

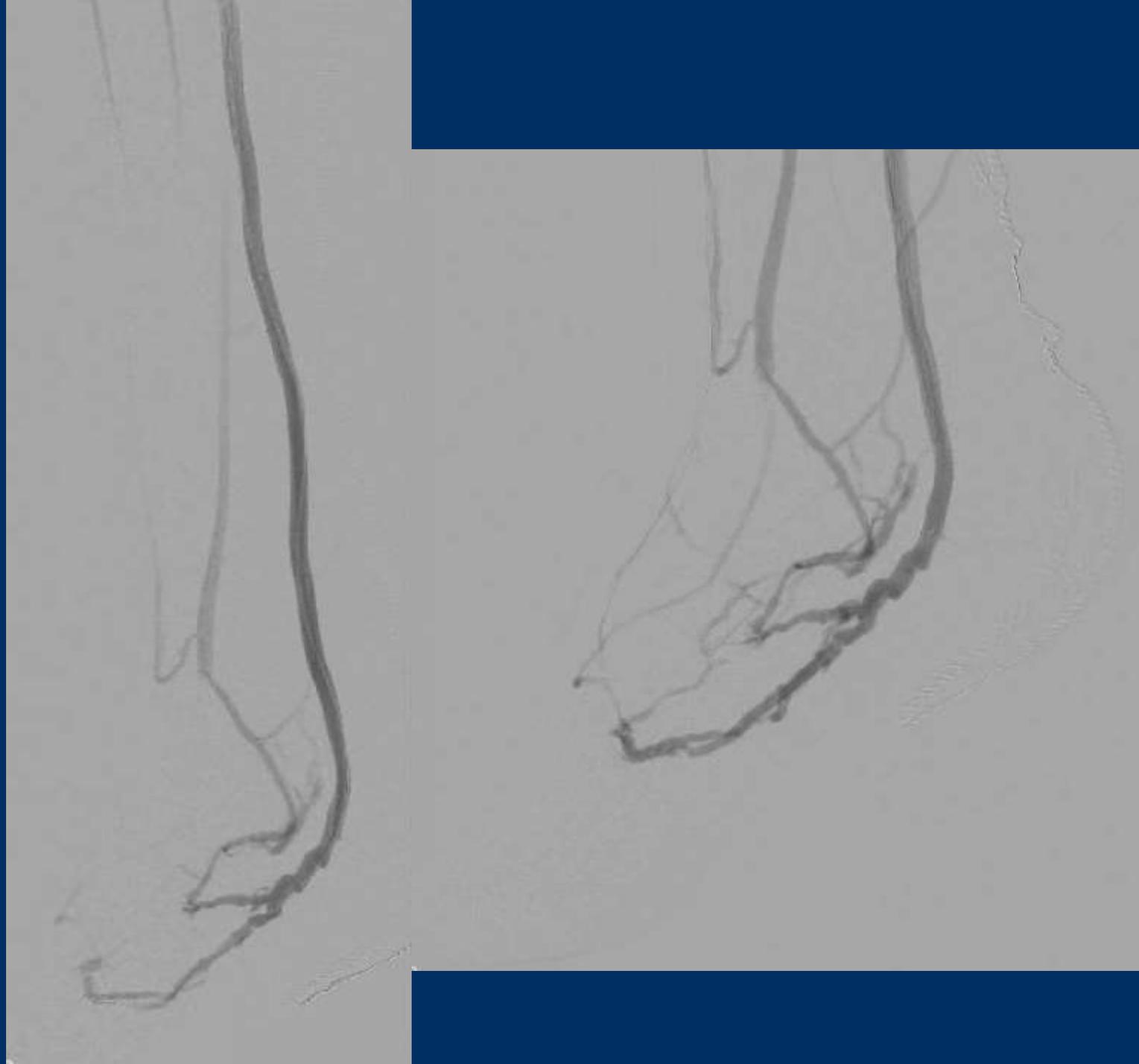
## Efficient Aspiration

- Continuous active aspiration, not using a peristaltic pump aspiration principle
- Minimizes embolization risk
- Large collection windows
- Internal mechanism further breaks down material as it is aspirated





**FIGURE 5.** Post adjunctive therapy result and distal run-off.







Thank You!

# Rotarex™

## Rotational Excisional Atherectomy System

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 haemodynamic 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  $\leq 2$  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 breach 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 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 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 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 the instructions 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:** Potential adverse effects include, but are not limited to: · 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