Peripheral Rotablator® Rotational Atherectomy System

Peripheral Rotablator® Rotational Atherectomy System:

**Purpose**

The Peripheral Rotablator® Rotational Atherectomy System is designed for the removal of obstructing lesions in the peripheral arteries. It is indicated for the treatment of arterial occlusions and stenoses that are not amenable to balloon angioplasty or stenting.

**System Components**

- **Rotablator Console**
- **Peripheral Rotaglide™ Lubricant**
- **Peripheral RotaWire™ Guide Wire**
- **WireClip™ Torquer**

**Indications for Use**

1. Angiographic evidence of significant stenosis or occlusion at lesion site.
2. Lesion length less than 20 cm.
3. Lesion diameter less than 4 mm.
4. Lesion location within the femoral or iliac arteries.
5. Lesion location within the popliteal arteries.

**Contraindications and Restrictions**

- The Peripheral Rotablator® Rotational Atherectomy System is contraindicated in patients with known allergy to the lubricant ingredients: olive oil, egg yolk phospholipids, glycerin, and sodium deoxycholate.
- The system is not recommended for patients with a history of arterial dissection or significant vessel wall abnormalities.

**Warnings**

- Use of the Peripheral Rotablator® Rotational Atherectomy System in the presence of flammable anesthetics is contraindicated.
- Do not operate the Rotablator Console with gas pressures in excess of 758.4 kPa (110 psi).

**Precautions**

- Use of the Peripheral Rotablator® Rotational Atherectomy System should only be performed at medical facilities where prompt treatment can be immediately performed in the event of a potentially injurious or serious complication.

**Operator’s Instructions**

- The system should only be used by physicians who have received adequate training in the proper use of the system.
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**Adverse Events**

The potential adverse reactions which may result from the use of this device include:

- 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

**Instructions for Use**

1. Ensure proper manipulation of the system 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

2. Do not allow the individual burr run time to exceed 30 seconds with total rotational procedure time not to exceed five minutes.

3. Do not allow the system when rotational or translational resistance occurs, as vessel perforation may occur.

4. Never advance the rotating burr by advancing the sheath. Guidewire 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.

5. If the Peripheral RotaLink Plus stops and 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 wireClip...

**Lubricant**

Rotaglide™ lubricant is contraindicated in patients with known allergies to the lubricant ingredients: olive oil, egg yolk phospholipids, glycerin, and sodium deoxycholate.

**Lubricant**

- **Rotaglide™ Lubricant** is intended for use with the Rotablator atherectomy system, for the purpose of increasing the lubricity of the system during the procedure.
- Use only normal saline including (but not limited to) anticoagulant and vasodilator therapy must be provided to the patient during all phases of patient care.
- When the thrombus has been resolved for two to four weeks, the lesion may be treated with the Rotablator Rotational Atherectomy System.

**Recommendations**

- The system should only be manipulated while they are under fluoroscopic observation with radiographic equipment that provides high resolution images.
- Use only normal saline including (but not limited to) anticoagulant and vasodilator therapy must be provided to the patient during all phases of patient care.
- When the thrombus has been resolved for two to four weeks, the lesion may be treated with the Rotablator Rotational Atherectomy System.

**Summary**

The Peripheral Rotablator® Rotational Atherectomy System is a safe and effective device for the removal of obstructing lesions in the peripheral arteries. It is recommended for use by experienced physicians who have received adequate training in its proper use. The system should only be used by physicians who have adequate training in the proper use of the system.

**References**

- Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only.
- Please see the complete “Directions for Use” for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator’s Instructions.
ADDRESS CALCIUM HEAD ON

Rotablator’s front-cutting ability gives you the confidence to engage tight, occluded lesions and provides stable rotation for concentric lumens.

Front-Cutting
Rotablator’s diamond-tipped burr is engineered to immediately engage the lesion, enabling precise control of ablation even in tight or occluded lesions.

Stable Rotation
Rotablator’s diamond-tipped burr spins concentrically on the wire, providing confidence even when treating small or tortuous vessels.

Total Control
Control the outcome with a symmetric burr that creates a smooth lumen at a specific diameter.

Control ablation with a burr that follows the wire.

Control embolic release with a 5-micron diamond-tipped burr that ablates plaque into micro-particles smaller in size than a red blood cell.

CONFIDENCE IN CALCIUM FOR OVER 20 YEARS

1990
Low complication rates from peripheral IDE clinical trial
n = 258 lesions
✔ 0.4% perforation
✔ 0.8% dissection/flap
✔ 0.8% occlusion
✔ 1.0% emboli
✔ 1.9% spasm
91% technical success

1995
76% primary patency at 14 months
n = 163 lesions
✔ 93% calcified lesions
✔ 61% ≤1 vessel run-off
97% technical success

2005
89% limb salvage rate at 13 months
n = 18 patients
✔ 89% CLI
✔ 72% Diabetic
100% technical success

### Peripheral Rotablator® Rotational Atherectomy System

**UPN** | **Catalog** | **Description**
--- | --- | ---
135 cm catheter length | M001410250 | 140-125 | 1.25 mm Peripheral RotaLink™ Plus, 5 F
| M001410150 | 140-150 | 1.50 mm Peripheral RotaLink™ Plus, 5 F
| M001410150 | 140-175 | 1.75 mm Peripheral RotaLink™ Plus, 6 F
| M001402000 | 140-200 | 2.00 mm Peripheral RotaLink™ Plus, 7 F
| M001402350 | 140-235 | 2.25 mm Peripheral RotaLink™ Plus, 7 F
| M001402500 | 140-250 | 2.50 mm Peripheral RotaLink™ Plus, 8 F

**Peripheral RotaWire™ Guide Wire and WireClip™ Torque**
330 cm length | M001373321 | 137-322 | Flouro Peripheral RotaWire (Box of 6)
| M001373311 | 137-331 | Floppy Peripheral RotaWire (Box of 6)

**Rotablator Console**

**UPN** | **Catalog** | **Description**
--- | --- | ---
22020020391 | H80222200031 | 22156-003 | Rotablator Console Kit (includes console, foot pedal and 20 ft. air supply hose)
| H80224360021 | 22156-003 | 20 ft Air Supply Hose – replacement
| H80221510101 | 22156-003 | Dynaglide™ Foot Pedal – replacement
| H80221560022 | 22156-003 | Console Power Cord – replacement

**Rotaglide lubricant**

**UPN** | **Catalog** | **Description**
--- | --- | ---
140-225 | M0011401750 | 140-150 | Peripheral RotaGlide™ Lubricant (Box of 6)
| M0011401750 | 140-125 | Peripheral RotaGlide™ Lubricant (Box of 6)

**Accessories**

**UPN** | **Catalog** | **Description**
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140-225 | M0011400002 | 141-006 | Peripheral RotaGlide™ Lubricant (Box of 6)
| H81251901101 | 150-081 | HTI Regulator Kit
| H80221600032 | 22196-003 | WireClip Torque (Box of 5)

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**Peripheral Interventions**

**300 Boston Scientific Way**

**Marlborough, MA 01752-1234**

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To order product or for more information contact customer service at 1-888-277-1201.

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