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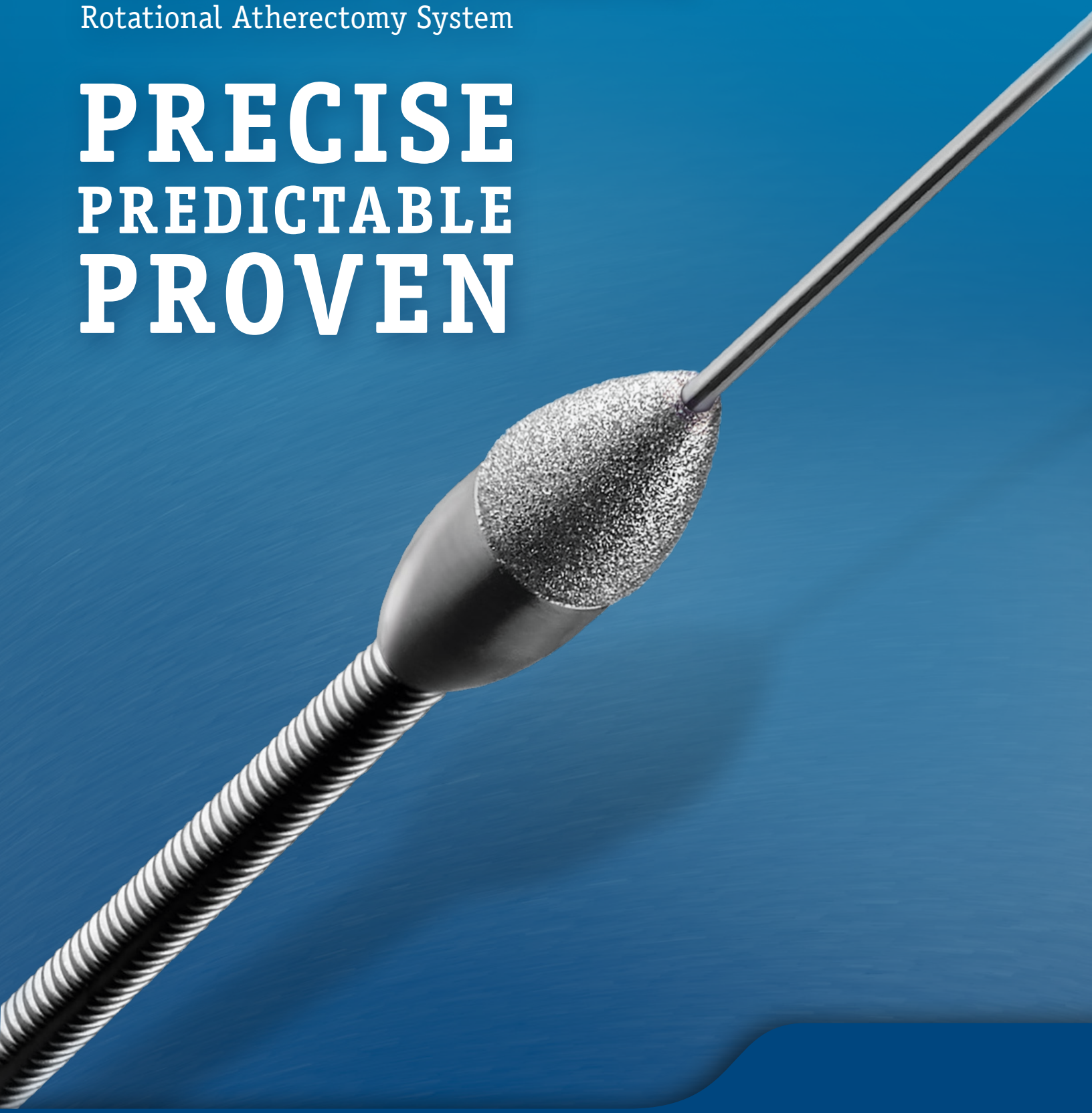
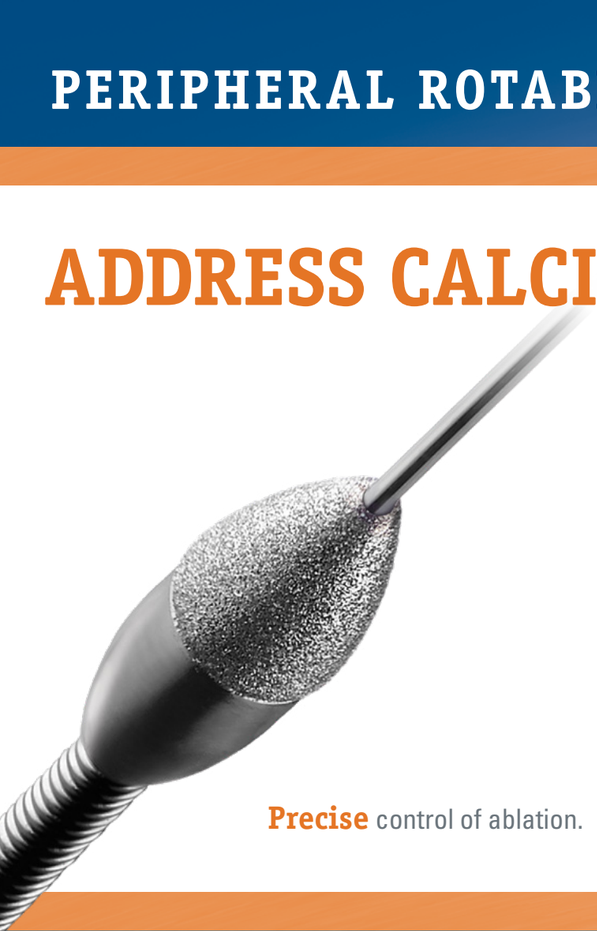
PERIPHERAL ROTABLATOR™

Rotational Atherectomy System

PRECISE
PREDICTABLE
PROVEN



PERIPHERAL ROTABLATOR™ Rotational Atherectomy System



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.

Precise control of ablation. **Predictable** lumen diameters. **Proven** technology.

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[1]
n= 258 lesions

- ✔ 0.4% perforation
- ✔ 0.8% dissection/flap
- ✔ 0.8% occlusion
- ✔ 1.0% emboli
- ✔ 1.9% spasm

91% technical success

1 Data on file. Peripheral Rotablator 510k submission K901206. (1990)

1995

76% primary patency
at 14 months[2]
n=163 lesions

- ✔ 93% ***calcified*** lesions
- ✔ 61% ≤ 1 vessel run-off

97% technical success

2 Henry M, Et al. Percutaneous Peripheral Atherectomy Using the Rotablator: A Single Center Experience. *J Endovasc Surg,* 1995;2:51-66.

2005

89% limb salvage rate
at 13 months[3]
n=18 patients

- ✔ 89% ***CLI***
- ✔ 72% ***Diabetic***

100% technical success

3 Dormal PA, Et al. Rotablator: A Forgotten Tool in Limb Ischemia? Acta Chir Belg. 2005; 105: 231-234

Peripheral Rotablator™ Rotational Atherectomy System

Peripheral RotaLink™ Plus Burr Catheter 135 cm catheter length, 0.009" OTW, 4.3 F (0.058") protective sheath		
UPN	**Catalog**	**Description**
M0011401250	140-125	1.25 mm Peripheral RotaLink Plus, 5 F
M0011401500	140-150	1.50 mm Peripheral RotaLink Plus, 5 F
M0011401750	140-175	1.75 mm Peripheral RotaLink Plus, 6 F
M0011402000	140-200	2.00 mm Peripheral RotaLink Plus, 7 F
M0011402250	140-225	2.25 mm Peripheral RotaLink Plus, 7 F
M0011402500	140-250	2.50 mm Peripheral RotaLink Plus, 8 F

Peripheral RotaWire™ Guide Wire and wireClip™ Torquer 330 cm length, 0.009" diameter body with 0.014" spring tip		
UPN	**Catalog**	**Description**
M0011373321	137-332	Extra Support Peripheral RotaWire (Box of 5)
M0011373311	137-331	Floppy Peripheral RotaWire (Box of 5)

Rotablator Console		
UPN	**Catalog**	**Description**
H802220200391	22020-039	Rotablator Console Kit (includes console, foot pedal and 20 ft. air supply hose)
H802216000031	21600-003	20 ft Air Supply Hose – replacement
H802224360021	22436-002	Dynaglide™ Foot Pedal – replacement
H802221510011	22151-001	Console Power Cord – replacement

Accessories		
UPN	**Catalog**	**Description**
M00114100062	141-0006	Peripheral RotaGlide™ Lubricant (Box of 6)
H80215901011	15901-01	HTI Regulator Kit
H802221960032	22196-003	WireClip Torquer (Box of 5)

ROTABLATOR™ ROTATIONAL ATHERECTOMY SYSTEM
CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.
Rotalink Plus INTENDED USE/INDICATIONS FOR USE: The Rotablator Rotational Atherectomy System is intended for percutaneous use in the peripheral vessels in patients with occlusive atherosclerotic disease who are acceptable candidates for endovascular procedures. **RotaWire: INDICATIONS FOR USE/INTENDED USE**:These guidewires are intended for use with the Rotablator Rotational Atherectomy System. **Lubricant INDICATIONS FOR USE:** Rotaglide lubricant is intended for use with the Rotablator atherectomy system, for the purpose of increasing the lubricity of the system. **CONTRAINDICATIONS AND RESTRICTIONS: Contraindications:** 1. Occlusions through which a guidewire will not pass. 2. Use in coronary arteries. 3. Long (≥ 20 cm) total occlusions. 4. Angiographic evidence of thrombus prior to treatment with the Rotablator Rotational Atherectomy System. Such patients may be treated with thrombolytics (e.g., Urokinase). When the thrombus has been resolved for two to four weeks, the lesion may be treated with the Rotablator Rotational Atherectomy System.5. Angiographic evidence of significant dissection at the treatment site. The patient may be treated conservatively for approximately four weeks to permit the dissection to heal before treating the lesion with the Rotablator Rotational Atherectomy System. **Lubricant CONTRAINDICATIONS:** Rotaglide™ lubricant is contraindicated in patients with known allergies to the lubricant ingredients: olive oil, egg yolk phospholipids, glycerin, sodium deoxycholate, L-histidine, disodium EDTA, sodium hydroxide, and water. **Restrictions** • Federal (USA) law restricts the use of this system to physicians who are credentialed in peripheral angioplasty and who have attended the Rotablator System Physician Training Program. **WARNINGS:** • The risks of Rotational Atherectomy can be reduced if the device and associated accessories are used in the appropriate patient population by a physician who has had adequate training.• If the Peripheral RotaLink Plus shows evidence of mechanical failure at any time prior to or during the angioplasty procedure, immediately discontinue use of the device and return it to Customer Service for evaluation. Do NOT attempt to use a damaged Peripheral RotaLink Plus; use may result in device malfunction and/or patient injury.• Never operate the Peripheral RotaLink Plus without saline infusion. Flowing saline is essential for cooling and lubricating the working parts of the advancer. Operation of the advancer without proper saline infusion may result in permanent damage to the advancer.• Never operate the Peripheral RotaLink Plus with the Rotablator Rotational Atherectomy System in Dynaglide™ mode or operate 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 docking port after the brake button is depressed. Defeating the brake, or operating the Peripheral RotaLink Plus with the Rotablator Rotational Atherectomy System in Dynaglide mode, without securing the guidewire may result in rotation and entanglement of the guidewire.• During setup of the Peripheral RotaLink Plus never grip or pull on the flexible shaft.• The burr at the distal tip of the Peripheral RotaLink Plus is capable of rotating at very high speeds. Do NOT allow parts of the body or clothing to come in contact with the burr. Contact may result in physical injury or entanglement. • Never 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.• If the Peripheral RotaLink Plus stops and the red STALL light on the console illuminates, retract the burr and immediately discontinue treatment. Check the advancer for proper connection to the console. If the connections are correct, use fluoroscopy to analyze the situation. Never force the system when rotational or translational resistance occurs, as vessel perforation may occur.• Never advance the rotating burr by advancing the sheath. Guidewire buckling may occur and perforation or vascular trauma may result. Always advance the rotating burr by using the advancer knob.• If resistance is encountered, retract the burr and stop treatment immediately. Use fluoroscopy to analyze the situation. Never force the Peripheral RotaLink Plus when rotational or translational resistance occurs, as vessel perforation, vessel trauma or embolism due to burr detachment or fractured wire may occur and in rare instances may result in surgical intervention and death.• The use of Rotablator Rotational Atherectomy System for in-stent restenosis might lead to damage of stent components and/or Peripheral RotaLink Plus, which may lead to patient injury. • Always keep the burr advancing or retracting while it is rotating. Maintaining the burr in one location 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 cm at a time in a smooth pecking motion, being careful to engage the lesion only minimally when resistance is met. Do not allow the individual burr run time to exceed 30 seconds with total rotational procedure time not to exceed five minutes. **RotaWire WARNINGS:** Use extreme caution and careful judgment in patients for whom anticoagulation is not indicated. **Console WARNINGS:** • Never use oxygen as the propellant for the Rotablator Rotational Atherectomy System. • The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the Rotablator System as replacement parts for internal components, may result in increased emissions or decreased immunity of the Rotablator System. • This device is not to be used in the presence of flammable anesthetics. • Do NOT operate the Rotablator Console with gas pressures in excess of 758.4 kPa (110 psi). • Do not modify or repair. **Lubricant WARNINGS:** Discard vial if there are particulates in the emulsion or if an oiling-out of emulsion has occurred. **PRECAUTIONS:** • Percutaneous rotational angioplasty with the Rotablator Rotational Atherectomy System should only be carried out at medical facilities where prompt treatment can be immediately performed in the event of a potentially injurious or serious complication. • Appropriate drug therapy including (but not limited to) anticoagulant and vasodilator therapy must be provided to the patient during all phases of patient care. • When the Peripheral RotaWire™ Guidewires and/or Peripheral RotaLink Plus are in the body, they should only be manipulated while they are under fluoroscopic observation with radiographic equipment that provides high resolution images. • Use only normal saline as the infusate. Never inject contrast agent, or any other substance that is not approved as part of the Rotablator Rotational Atherectomy System, into the infusion port or saline infusion bag as this may cause permanent damage to the Peripheral RotaLink Plus. **Console PRECAUTIONS:** •User should take precautions when using the console in conjunction with other medical electrical equipment. • The Rotablator Console needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in Appendix D in the DFU. **ADVERSE EVENTS:** Potential adverse reactions which may result from the use of this device include but are not limited to: • 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 and vessel occlusion • Vessel trauma (dissection, perforation, psudoaneurysm, arteriovenous fistula) There may also be complications associated with distortion, kinks, and fracture of the guidewire and physical deterioration or malfunction of the device, which can lead to patient injury or death. **91059041 Rev/Ver. AC**

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To order product or for more information contact customer service at 1.888.272.1001.

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