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DIRO: 1st Direct Comparison of Rotational & Orbital Atherectomy

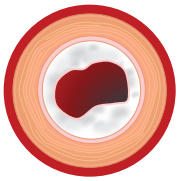
ROTAPRO™ Rotational Atherectomy System shown to deliver optimal lumen gain in severely calcified lesions

Study Design

Investigator-Led | Randomized | Single-Center, Japan

Patients

N = 100 with baseline OCT showing de novo lesions with calcium arc > 180 or moderate/severe calcification by angiography when OCT could not advance distal to lesion.*



Primary endpoints

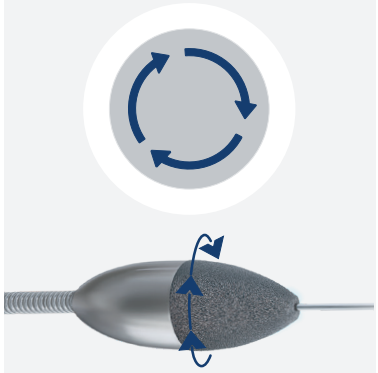
- Stent expansion (MSA/Distal reference lumen area)
- Plaque modification

Study endpoints also included OCT findings and other procedural outcomes.

Head-to-Head Atherectomy Devices

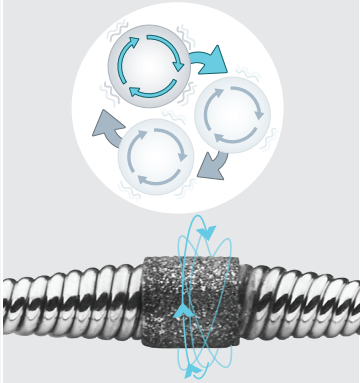
Rotational

Mechanism of Action:
Diamond-tipped burr spins in uniform concentric circles.



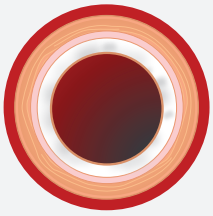
Orbital

Mechanism of Action:
Offset crown oscillates in an unpredictable orbital path.

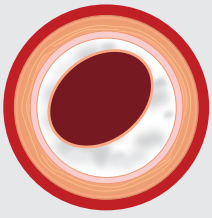


Study Results

Significantly greater maximum plaque modification area
demonstrated by the **Rotational Atherectomy Group**
(P < 0.01)

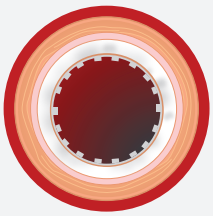


1.24 mm²
Rotational Atherectomy

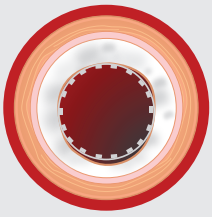


0.89 mm²
Orbital Atherectomy

Significantly greater stent expansion**
demonstrated by the **Rotational Atherectomy Group**
(P < 0.02)



99.5%
Rotational Atherectomy



90.6%
Orbital Atherectomy

Learn more about the ROTAPRO™ System:

SEE PREP TREAT

* Key exclusion criteria for the study included Ostial LM or ostial RCA, patients who may be pregnant, and patients with a life expectancy <12 mo.
**Assessed by Distal Reference.
Illustrations shown are for education purposes only, not indicative of actual size or clinical outcome.

ROTAPRO™
Rotational Atherectomy System

1. Okamoto, N; Japanese Circulation Society 2023.

ROTAPRO™ Rotational Atherectomy System Percutaneous rotational coronary atherectomy with the ROTAPRO Rotational Atherectomy System, as a sole therapy or with adjunctive percutaneous coronary intervention (PCI) is indicated in patients with calcific coronary artery disease who meet one of the following selection criteria: • Single vessel atherosclerotic coronary artery disease with a stenosis that can be passed with a guidewire; • Multiple vessel coronary artery disease that in the physician's judgment does not pose undue risk to the patient; • Patients who have had prior PCI, and who have native coronary artery post-balloon angioplasty restenosis; or, • Native vessel atherosclerotic coronary artery disease that is less than 25 mm in length. **CONTRAINDICATIONS AND RESTRICTIONS Contraindications** 1. Stenoses through which a guidewire will not pass. 2. Last remaining vessel with compromised left ventricular function. 3. Saphenous vein grafts. 4. Angiographic evidence of thrombus. 5. Angiographic evidence of significant dissection at the treatment site. **Restrictions** Rotational atherectomy should be performed only by physicians trained in percutaneous interventional procedures. **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. • Never operate the ROTAPRO System without saline infusing. • Never operate the ROTAPRO Advancer in Dynaglide™ mode or operate the guidewire brake defeat button unless you have a firm grip on the guidewire using the wireClip™ torquer. • The burr at the distal tip of the RotaLink Catheter is capable of rotating at very high speeds. Do NOT allow parts of the body or fabric 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 ROTAPRO Advancer stops and the red STALL indicator on the console illuminates, retract the burr and immediately discontinue treatment. Never force the system when rotational or translational resistance is encountered, as guidewire or vessel damage (such as perforation) may occur. • Always advance the rotating burr by using the advancer knob. • If resistance is encountered, retract the burr and stop treatment immediately. Never force the ROTAPRO™ Advancer 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 ROTAPRO for in-stent restenosis might lead to damage of stent components and/or ROTAPRO System, which may lead to patient injury. **• Do not attempt to treat lesion while the ROTAPRO System is in Dynaglide™ mode.** Always keep the burr advancing or retracting while it is rotating. It is best to advance and retract 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. Short individual runs of less than 30 seconds are recommended with total rotational procedure time not to exceed five minutes. **ROTAPRO CONSOLE SPECIFIC WARNINGS**: • Never use oxygen as the propellant for the ROTAPRO Rotational Atherectomy System. • The use of accessories, other than those specified, with the exception of those sold by the manufacturer of the ROTAPRO System as replacement parts for internal components, may result in increased emissions or decreased immunity of the ROTAPRO System.• This device is not to be used in the presence of flammable anesthetics.• Do NOT operate the ROTAPRO Console with gas pressures in excess of 758.4 kPa (110 psi), as a gas hose may burst. • Do not modify or repair beyond replacement of fuses as described in Service Information. **PRECAUTIONS** • Treating certain types and/or locations of lesions or patients with certain conditions is inherently riskier, regardless of the therapeutic device being used. Physicians should be aware of the higher risk when treating patients, such as: 1. Patients who are not candidates for coronary artery bypass surgery; 2. Patients with severe, diffuse three-vessel disease (multiple diseased vessels should be assessed for treatment in separate sessions); 3. Patients with unprotected left main coronary artery disease; 4. Patients with ejection fraction less than 30%; 5. Lesions longer than 25 mm; 6. Angulated (≥ 45°) lesions. • When performing percutaneous rotational atherectomy with the ROTAPRO System on-site surgical backup should be included as a clinical consideration. • Appropriate drug therapy including (but not limited to) anticoagulant/antiplatelet and vasodilator therapy must be provided to the patient during all phases of patient care. • A temporary pacemaker may be necessary and is particularly recommended during the treatment of lesions in a dominant right coronary or circumflex artery to resolve profound bradycardia which may occur. • Use only normal saline as the infusate. **ROTAPRO CONSOLE SPECIFIC PRECAUTIONS**:• User should take precautions when using the console in conjunction with other medical electrical equipment. • The ROTAPRO Console requires special precautions regarding Electromagnetic Compatibility (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: • Angina • Arrhythmias • Bailout stenting• Conduction block • Death • Drug reaction, allergic reaction to contrast media • Electric shock • Embolism (coronary, cerebral, peripheral) • Hemorrhage or hematoma • Infection, local or systemic • Myocardial ischemia • Myocardial infarction • Pericardial effusion/cardiac tamponade • Pulmonary edema/cardiogenic shock • Slow flow, no reflow, abrupt vessel closure • Stroke • Thrombus formation • Vessel spasm • Vessel trauma (dissection, perforation, rupture or injury) There may also be complications associated with distortion, kinks, and fracture of the guidewire and physical deterioration or malfunction of the system, which can lead to patient injury or death. In addition, some of the above potential adverse events may require additional surgical intervention. **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. 92243415 B

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IC-1612006-AA