

ROTABLATOR™

Rotational Atherectomy System

Reference Guide

Please consult device DFU for full Operating Instructions

Technical Assistance: 1.800.949.6708

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System Set-Up

- Connect foot pedal to console (3 connections) **A**
- Connect air hose to air supply
- Connect air supply to console **B**
- Open gas tank to pressurize system
- Check gauges to ensure proper system pressure
(min 500 psi in the tank / 90–110 psi to the console)



Console Front



Console Back



Console Back

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System Set-Up

Pre-Procedure System Test

Test system outside body with foot pedal activated

- D** Drip: Verify irrigation at distal tip of burr catheter
- R** Rotation: Set burr speed to desired RPM level
- A** Advancement: Confirm advancer knob and burr move freely
- W** Wire: Verify brake is holding guidewire while burr is spinning and wire clip is affixed

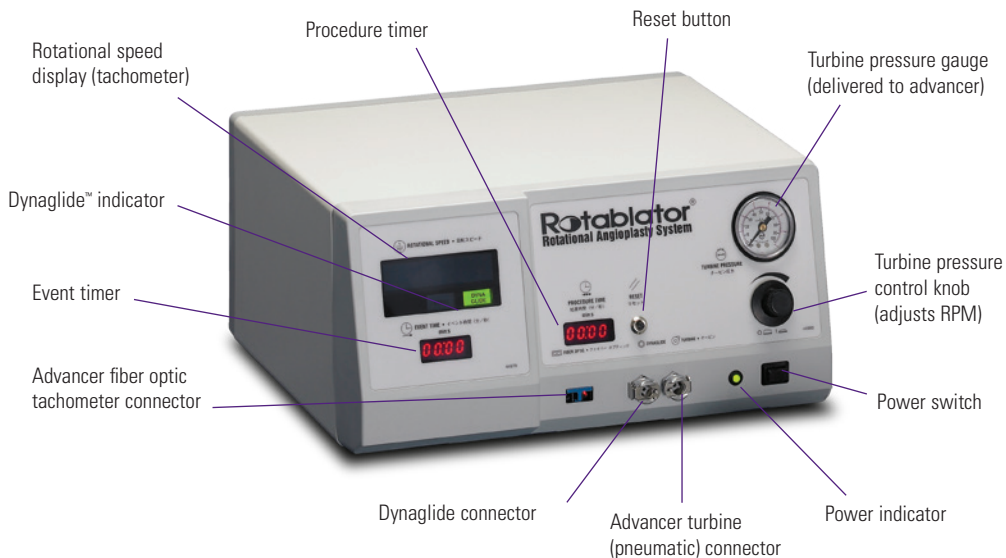


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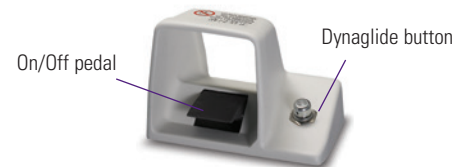
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System Overview

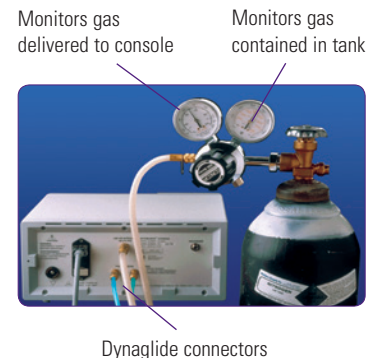
Console



Foot Pedal



Air Supply

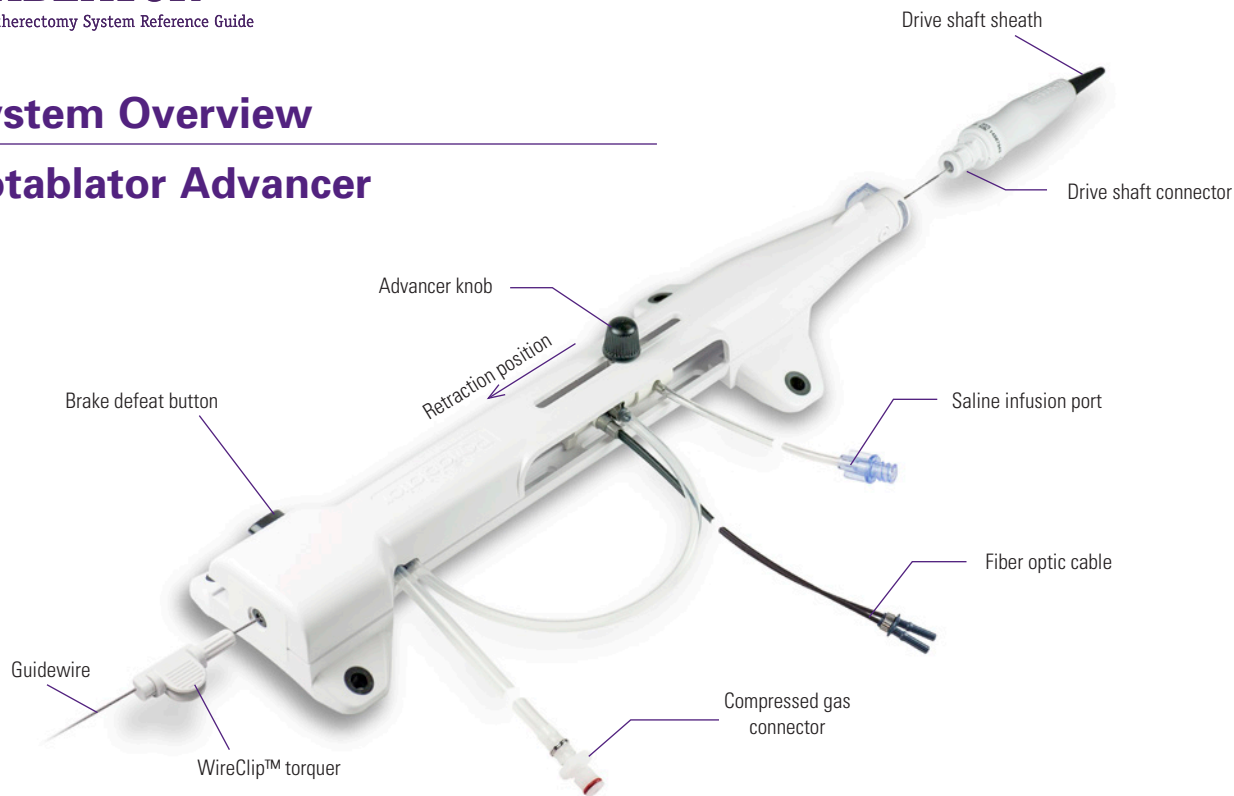


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System Overview

Rotablator Advancer



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System Overview

Burr Sizes

A wide selection of burr sizes provides flexibility to treat any size occlusion (0.35 mm to 2.5 mm).



(Also available in 2.15, 2.25, 2.38, and 2.50 mm)

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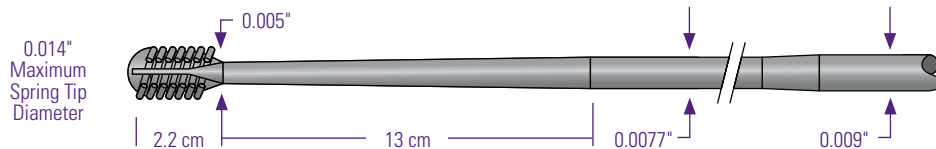
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System Overview

Wires

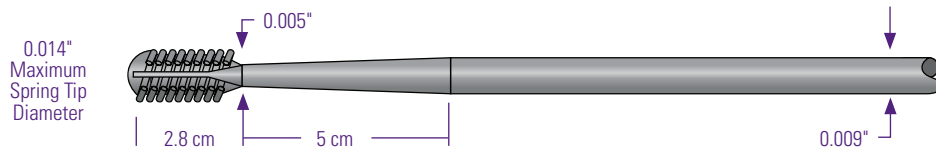
Floppy

- 325 cm total length
- Flexible and torqueable
- Reduced guidewire bias



Extra Support

- 325 cm total length
- More supportive guidewire characteristics



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System Overview

Rotaglide™ Lubricant*

- Inject one 20 cc vial into 1000 cc saline flush bag
- Reduces friction and improves tactile feel
- Reduces sudden drops in RPMs caused by lesion feedback
- Reduces heat generation
- Contraindicated if patient is allergic to eggs or olive oil
- Does not require refrigeration



**Ingredients: Olive oil, egg yolk, phospholipids, sodium deoxycholate, L-histidine, disodium EDTA, sodium hydroxide, water*

Guide Catheter Selection & Sizing

Guide sizes are based on larger lumen catheters.

Burr (mm)	Diameter (Inches)	Minimum Recommended Guide Catheter Internal Diameter (Inches)	Recommended Guide Catheter (French) ^{*,†}
1.25	0.049	0.060 [‡]	6.0
1.50	0.059	0.063	6.0
1.75	0.069	0.073	7.0
2.00	0.079	0.083	8.0
2.15	0.085	0.089	8.0
2.25	0.089	0.093	9.0
2.38	0.094	0.098	9.0
2.50	0.098	0.102	10.0

* Inside guide catheter diameter and french size may differ among manufacturers. Ensure guide is compatible with the largest burr intended to be used.

† Sheath size is the determinant of the minimum ID on the 1.25 mm burr.

‡ Add 0.004" to burr diameter to calculate minimum ID needed

Recommended Guide Catheter Curves

Right: FR4, Multipurpose **Left:** Q-Curve™, CLS™, Left Back-Up

(Guide catheters with side holes can help to improve flow.)

Recommended Burr Speed

Small Burrs (1.25 mm–2.0 mm): 160,000–180,000 RPM

Large Burrs (≥ 2.15 mm): 140,000–160,000 RPM

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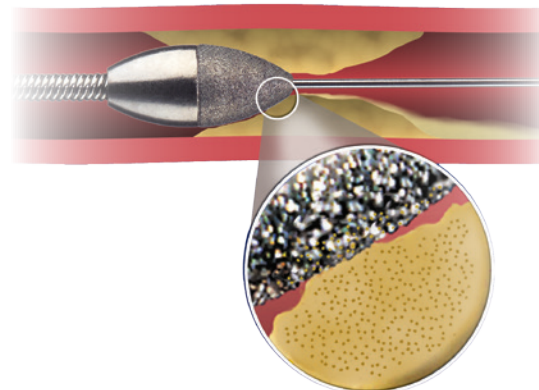
Atherectomy Procedure

Burr Positioning

- Lock advancer knob 2–3 cm forward and advance into guide catheter
- When the burr is 1–2 cm proximal to the lesion, relieve any forward tension on the drive shaft by unlocking advancer knob and pulling it back

Ablation

- Advance burr in a smooth back and forth pecking motion until all the way through the lesion
- Maintain RPMs within 5,000 of platform speed
 - Limit runs to < 30 seconds with rest periods in between
- Upsize burr in 0.25 mm increments if necessary
- Total rotational procedure time should not exceed five minutes
- Finish with one polishing run
 - No RPM drop
 - Should be little to no resistance



Atherectomy Procedure (continued)

Burr Removal

- Press Dynaglide™ button on foot pedal (Dynaglide indicator on console will light)
- Press brake defeat on advancer while holding WireClip™ Torquer
- Press foot pedal for low-speed rotation in Dynaglide mode
- Retract Rotablator Catheter while assistant holds WireClip Torquer and advances guidewire simultaneously to maintain guidewire position
- Press Dynaglide button to reactivate normal mode after catheter is removed from patient

Burr Upsizing

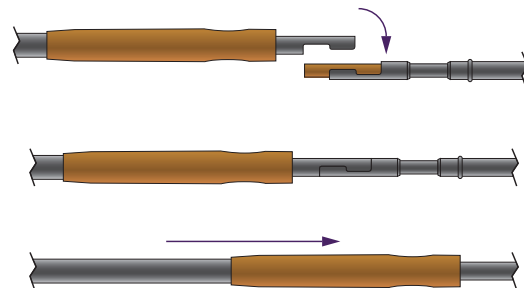
- Utilize IVUS to properly assess reference vessel diameter
- Step up burr sizes in next catheter size increments (0.25 mm increments)
 - Ensure guide catheter accommodates burr size



Atherectomy Procedure (continued)

Rotalink™ Advancer / Burr Connection–Key Steps*

- Loosen advancer knob, slide forward exposing drive shaft connection—tighten knob. Slide back copper sheath and align catheter drive shaft and advancer drive shaft.
- Position inner-drive shaft into spoon of burr catheter
Snap interlocks together
- Slide copper sheath over interlock connection, feeling a snap as it locks
- Test for successful connection by tugging
Loosen advancer knob (retract while holding catheter)
Push catheter body into advancer firmly until it snaps into place



* Never operate the Advancer without saline infusion. Flowing saline is essential for cooling and lubricating working parts of the advancer.

Troubleshooting

Burr stops, stalls, or does not reach desired platform speed – Inside the body

- Check that the hemostasis valve is not overly tightened to avoid crimping catheter
- Evaluate the guide catheter for kinks
- Determine if the saline flush was infusing during testing; if not, the motor drive could be affected
- If the burr is a 1.25 mm or 1.5 mm, the burr could be lodged within the sheath. Push advancer control knob completely forward to dislodge. Leave the burr control knob completely forward and re-advance the burr to the lesion.
- If the burr has lodged in the lesion, cease rotational atherectomy and carefully attempt to remove the device. Never attempt to start the burr spinning if it has stalled within the lesion.
 - Don't pull on the catheter
 - Administer nitro
 - Wait 30 seconds, try dislodging the burr again
 - Use buddy wire and balloon to help expand
 - Use Dynaglide™ Foot Pedal for quick burp

Rotablator system customer complaints should be forwarded to the Complaint Call Center (1.800.811.3211)

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Troubleshooting (continued)

Burr stops, stalls, or does not reach desired platform speed – Outside the body

- Check pressure coming from air source (90–110 psi)
- Check volume of air supply in tank (>500 psi)
- Check all lines and tubing to ensure they are kink free and connections are tight
- Ensure DynaGlide™ mode is turned off
- Check saline connection and make sure drip increases when burr is activated
- Check for kinks in the drive shaft
- Confirm that burr is not in contact with drapes or the hemostasis valve
- Check that guidewire is kink free

Burr becomes detached

- Do not turn on the air turbine
- Carefully advance the non-rotating drive shaft and retract the burr and guidewire until the distal tip of the drive shaft and proximal tip of the burr are in contact
- Withdraw the drive shaft, burr, and guidewire as a unit with tension applied on the guidewire to keep the burr adjacent to the distal end of the drive shaft
- Inject IV nitroglycerin to relieve any spasm

Troubleshooting (continued)

Blank RPM display during procedure

- Check to see that the foot pedal is fully depressed

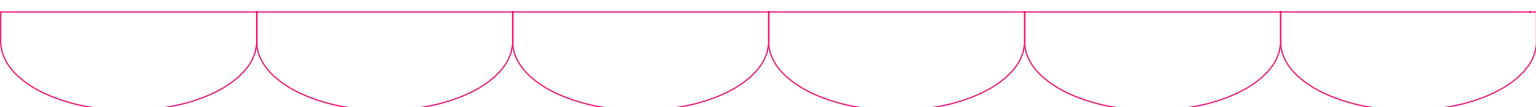
Burr spins after foot pedal is released

- Turn down the rotational speed on the console to the burr exchange speed (60,000 to 90,000 RPM)
- Retract the burr from the artery using the burr exchange technique, discontinue use of the Rotablator system and contact customer service

Regulator / Air supply emits a hissing noise

- Check dual-gauge regulator connection to air supply and tighten connection until hissing stops; if hissing persists, replace the Teflon™ tape around the fitting
- Check the Rotablator device quick disconnect in the regulator for leaking; if air leak persists, remove the connector and replace the Teflon tape

Console emits a hissing noise

- Dual-gauge regulator setting should be between 90–100 psi
 - Ensure all air hoses are tightly connected and not kinked
 - Advancer may be defective (replace advancer)
- 

Troubleshooting (continued)

Console stall light comes on

- As a safety feature, system automatically stalls when the RPM drops below 15,000 for 1.5 seconds or more
- Release the foot pedal to clear the stall condition
- Examine the air hose for kinking
- Check advancer connections and then depress the foot pedal to continue
- Ensure console is plugged in, correctly set-up and connected
- Double check airflow regulator to secure tank connections and quantity of pressure output tank

The advancer was running, but now is not

- Check all connections
- Check air source—make sure it is on and delivering 90–110 psi
- Check for possible lack of saline which can cause “burn out”
- A new advancer may be needed if no saline drip through the advancer

There is blood in the sheath

- Discontinue treatment; verify that the saline infusion is properly connected, pressurized, and flowing
- If the device is properly connected and blood continues to flow up the sheath, replace the RotaLink™ Catheter with a new device

Frequently Asked Questions

Can I use house air as opposed to the air tank?

- Yes. Ensure that house air is delivering 90–110 psi to the console.

What is a Rota Cocktail?

- Pharmacological agents such as nitroglycerine, verapamil, heparine, etc. have been used routinely with the flush solution. Boston Scientific does not prescribe the contents of the Rota cocktail.

Why is there a white substance on the guidewire?

- This is a lubricant called Hystrene™ to facilitate initial burr passage over a dry wire; do not wipe this compound off the guidewire

What clearance is needed for burrs through guide catheters *(See System Overview: Guide Catheter Selection & Sizing)*

- 0.004" required. Add 0.004" to burr diameter to calculate minimum ID needed

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Frequently Asked Questions *(continued)*

How do I order an Airgas Regulator?

- Part #H80215901-011

Need brass fitting–Rectus Type 21 Adapter

- Affixes directly to Airgas regulator or house air line
- Provided with Airgas regulator ordered from Boston Scientific

Who do we contact for physician proctoring?

- Contact your Boston Scientific sales representative

RotaWire™ Guide Wire

Order Number	Model/Description	Length	Tip Length	Flexibility	Spring Tip Diameter	Maximum Diameter	Quantity
H802 23239-001 2	RotaWire Extra Support Guide Wire with WireClip™ Torquer	330 cm	2.8 cm	Stiff	0.009 in	0.014 in	Box of 5
H802 22824-002 2	RotaWire Floppy Guide Wire with WireClip Torquer	330 cm	2.2 cm	Flexible	0.009 in	0.014 in	Box of 5

RotaLink™ System Catheter and Burr

Order Number	Model/Description	Burr Size	Length	Maximum Diameter
H802 22782-001A 0	Rotablator RotaLink Advancer (separate from catheter and burr)			
H802 22768-002 0	RotaLink Exchangeable Burr Catheter	1.25 mm	135 cm	0.58 in
H802 22768-003 0	RotaLink Exchangeable Burr Catheter	1.50 mm	135 cm	0.58 in
H802 22768-004 0	RotaLink Exchangeable Burr Catheter	1.75 mm	135 cm	0.58 in
H802 22768-005 0	RotaLink Exchangeable Burr Catheter	2.00 mm	135 cm	0.58 in
H802 22768-015 0	RotaLink Exchangeable Burr Catheter	2.15 mm	135 cm	0.58 in
H802 22768-006 0	RotaLink Exchangeable Burr Catheter	2.25 mm	135 cm	0.58 in
H802 22768-016 0	RotaLink Exchangeable Burr Catheter	2.38 mm	135 cm	0.58 in
H802 22768-007 0	RotaLink Exchangeable Burr Catheter	2.50 mm	135 cm	0.58 in

RotaLink™ Plus Pre-Connected Exchangeable Rotational Atherectomy System

Order Number	Model/Description	Burr Size	Length	Maximum Diameter
H749 23631-002 0	RotaLink Pre-connected Exchangeable Burr Catheter and Advancing Device	1.25 mm	135 cm	0.58 in
H749 23631-003 0	RotaLink Pre-connected Exchangeable Burr Catheter and Advancing Device	1.50 mm	135 cm	0.58 in
H749 23631-004 0	RotaLink Pre-connected Exchangeable Burr Catheter and Advancing Device	1.75 mm	135 cm	0.58 in
H749 23631-005 0	RotaLink Pre-connected Exchangeable Burr Catheter and Advancing Device	2.00 mm	135 cm	0.58 in
H749 23631-015 0	RotaLink Pre-connected Exchangeable Burr Catheter and Advancing Device	2.15 mm	135 cm	0.58 in
H749 23631-006 0	RotaLink Pre-connected Exchangeable Burr Catheter and Advancing Device	2.25 mm	135 cm	0.58 in
H749 23631-016 0	RotaLink Pre-connected Exchangeable Burr Catheter and Advancing Device	2.38 mm	135 cm	0.58 in
H749 23631-007 0	RotaLink Pre-connected Exchangeable Burr Catheter and Advancing Device	2.50 mm	135 cm	0.58 in

Console

Order Number	Model/Description	Voltage
H802 22020-039 1	System Console, RC5000 Rotablator™ Console, SERV	115 VAC
H802 22020-039L	Refurbished Rotablator Console	115 VAC

Accessories

Order Number	Model/Description	Quantity
H802 21600-003 1	Replacement Braided Air Supply Hose (20 feet)	Single
H802 22436-002 1	Dynaglide™ Foot Pedal	Single
H802 22151-001 1	Power Cord—North America	Single
H802 15901-01 1	Byrne Regulator	Single
H802 22196-003 2	WireClip™ Torquer	Box of 5

Rotaglide™ Lubricant

Order Number	Model/Description	Quantity
H749 23548-001 62	Rotaglide Lubricant Mixture 20 cc vials	Box of 6

The C-code used for this product is C1724, Catheter, transluminal atherectomy, rotational. C-codes are used for hospital outpatient device reporting for Medicare and some private payers.

Note: Boston Scientific is not responsible for the correct use of codes on submitted claims; this information does not constitute reimbursement or legal advice.

For Technical Assistance contact: 1.800.949.6708

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Rotablator Rotational Atherectomy System

Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events and Operator's Instructions.

Intended Use/Indications for Use: Percutaneous rotational coronary angioplasty with the Rotablator Rotational Atherectomy System, as a sole therapy or with adjunctive balloon angioplasty, is indicated in patients with coronary artery disease who are acceptable candidates for coronary artery bypass graft surgery and 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
- Certain patients who have had prior percutaneous transluminal coronary angioplasty (PTCA), and who have a restenosis of the native vessel or,
- Native vessel atherosclerotic coronary artery disease that is less than 25 mm in length.

Contraindications and Restrictions

Contraindications:

1. Occlusions 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 prior to treatment with the Rotablator 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 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 System.

Restrictions: Federal (USA) law restricts the use of this system to physicians who are credentialed in 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. The use of Rotablator for in-stent restenosis might lead to damage of stent components and/or Rotablator System, which may lead to patient injury.

Precautions: Treating certain types and/or locations of lesions or patients with certain conditions is inherently riskier, regardless of the therapeutic device being used. For many of these applications, relatively few cases have been carried out using the Rotablator System. Physicians should be aware of the higher risk when treating such patients and the lack of scientific evidence for treatment in the following applications:

1. Patients who are not candidates for coronary artery bypass surgery
2. Patients with severe, diffuse three-vessel disease (multiple diseased vessels should be treated 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 ($\geq 45^\circ$) lesions. There has been limited experience with the brachial approach.

Adverse Events: Potential adverse reactions which may result from the use of this device include but are not limited to: • Angina or unstable angina • Arrhythmias • Bailout stenting

• Cardiac perforation • Cardiac tamponade
• Conduction block • Coronary artery spasm
• Death • Drug reactions, allergic reaction to contrast medium • Embolism (coronary, cerebral, peripheral) • Hemorrhage or hematoma • Infection, local infection, systemic infection • Myocardial ischemia
• Myocardial infarction (Q-wave and non Q-Wave) • Pericardial effusion • Pulmonary edema/cardiogenic shock • Slow flow, no flow, abrupt vessel closure • Stroke
• Vascular thrombus • 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.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

**Boston
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Advancing science for life™

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

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