

For technical assistance, contact **1.800.949.6708**

## 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  
(min 500 psi in the tank / 90–110 psi to the console)

## Using Rotaglide™

- Inject one vial into a 1000 mL sterile saline bag
- Roll bag to mix solution

## Component Set-Up

- Attach advancer to the console (3 connections) **C**
- Attach saline infusion port to irrigation source  
(inflate to ~200 mmHG)
- Open irrigation line
- Backload burr catheter onto guidewire
- Connect wire clip torquer

business card holder

## 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

## 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.

### 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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#### **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: • Occlusions through which a guidewire will not pass. • Last remaining vessel with compromised left ventricle function. • Saphenous vein grafts. • 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. • 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: • Patients who are not candidates for coronary artery bypass surgery; • Patients with severe, diffuse three-vessel disease (multiple diseased vessels should be treated in separate sessions); • Patients with unprotected left main artery disease; • Patients with ejection function less than 30%; • Lesions longer than 25 mm; • Angulated (> or = 45 degree) lesions. • Percutaneous rotational angioplasty with the Rotablator System should only be carried out at hospitals where emergency bypass surgery can be immediately performed in the event of a potentially injurious or life threatening complication.

**Adverse Events:** Potential adverse events which may result from 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 of the device, which can lead to patient injury or death.

**Complications:** Complications include: access site bleeding of significance, distal embolization, intimal dissection, acute vessel closure, vessel perforation or tear, ventricular perforation, emergency surgery, contrast media reaction, stroke, slow flow, no flow, myocardial infarction, arrhythmia requiring treatment, cardiac tamponade, and death.

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

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