Reference Guide
Please consult device DFU for full Operating Instructions
System Set-Up

- Connect foot pedal to console (*3 connections*)
- Connect air hose to air supply
- Connect air supply to console
- Open gas tank to pressurize system
- Check gauges to ensure proper system pressure
  (min 34.4 bars in the tank / 6.2 - 7.6 bars to the console)
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 and verify Dynaglyde speed

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
System Overview

Console

- Rotational speed display (tachometer)
- Procedure timer
- Reset button
- Turbine pressure gauge (delivered to advancer)
- Dynaglide™ indicator
- Event timer
- Advancer fiber optic connector
- Dynaglide connector
- Advancer turbine (pneumatic) connector
- Power switch
- Power indicator

Foot Pedal

- On/Off pedal
- Dynaglide button

Air Supply

- Monitors gas delivered to console
- Monitors gas contained in tank
- Dynaglide connectors
System Overview

ROTABLATOR™ Advancer

- Drive shaft sheath
- Drive shaft connector
- Advancer knob
- Retraction position
- Brake defeat button
- Saline infusion port
- Fiber optic cable
- Compressed gas connector
- Guidewire
- WireClip™ torquer
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)
Floppy
• 325 cm total length
• Flexible and torqueable
• Reduced guidewire bias

Extra Support
• 325 cm total length
• More supportive guidewire characteristics
<table>
<thead>
<tr>
<th>Burr (mm)</th>
<th>Diameter (cm)</th>
<th>Minimum Recommended Guide Catheter Internal Diameter (cm)</th>
<th>Recommended Guide Cathether (French)*,†</th>
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</thead>
<tbody>
<tr>
<td>1.25</td>
<td>0.13</td>
<td>0.15†</td>
<td>6.0</td>
</tr>
<tr>
<td>1.50</td>
<td>0.15</td>
<td>0.16</td>
<td>6.0</td>
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<tr>
<td>1.75</td>
<td>0.18</td>
<td>0.19</td>
<td>7.0</td>
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<td>2.00</td>
<td>0.20</td>
<td>0.21</td>
<td>8.0</td>
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<tr>
<td>2.15</td>
<td>0.22</td>
<td>0.23</td>
<td>8.0</td>
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<tr>
<td>2.25</td>
<td>0.23</td>
<td>0.24</td>
<td>9.0</td>
</tr>
<tr>
<td>2.38</td>
<td>0.24</td>
<td>0.25</td>
<td>9.0</td>
</tr>
<tr>
<td>2.50</td>
<td>0.25</td>
<td>0.26</td>
<td>10.0</td>
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</table>

* 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” (0.10 mm) to burr diameter to calculate minimum ID needed.

European expert consensus on rotational atherectomy recommendations:

**GUIDE CATHETER SELECTION:**
Most procedures can be performed with a 6 FR GC which can accommodate burrs up to 1.5 mm
A single curve that gives strong support is recommended.

**Right:** FR4; Multipurpose **Left:** Q Curve®, CLST™

**PROCEDURAL RECOMMENDATIONS**
**ABLATION SPEED:** Between 135,000 and 180,000 RPM to reduce risk of complications
**RUN TIME** Short duration: individual runs should be no longer than 30 secs
**DECELERATION** should be < 5,000 RPM

1 Barbato E et al. European expert consensus on rotational atherectomy. Eurointervention, 2015; 11:30-36
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, in multiple runs (if needed) until all the way through the lesion
- Deceleration should be less than 5000 RPM from the set-up speed
  - individual runs < 30 secs 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 (Push and Pull Technique)

• 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
Troubleshooting (continued)

**Burr stops, stalls, or does not reach desired platform speed – Outside the body**
- Check pressure coming from air source (6.2 - 7.6 bars)
- Check volume of air supply in tank (>34.4 bars)
- 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 detachment**
- 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 if 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 6,2 - 7,6 bars
- 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 0.5 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 6.2 - 7.6 bars
- 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 6.2 - 7.6 bars 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" (0.10 mm) required. Add 0.004" (0.10 mm) to burr diameter to calculate minimum ID needed

Who do we contact for physician proctoring?
   – Contact your Boston Scientific sales representative
### ROTAWIRE™ Guidewire

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Model/Description</th>
<th>Length</th>
<th>Tip Length</th>
<th>Flexibility</th>
<th>Spring Tip Diameter</th>
<th>Maximum Diameter</th>
<th>Quantity</th>
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<tbody>
<tr>
<td>H802 23239-001</td>
<td>ROTAWIRE Extra Support Guidewire with WireClip™ Torquer</td>
<td>330 cm</td>
<td>2.8 cm</td>
<td>Stiff</td>
<td>0.014 in (0.36 mm)</td>
<td>0.009 in (0.23 mm)</td>
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<tr>
<td>H802 22824-002</td>
<td>ROTAWIRE Floppy Guidewire with WireClip Torquer</td>
<td>330 cm</td>
<td>2.2 cm</td>
<td>Flexible</td>
<td>0.014 in (0.36 mm)</td>
<td>0.009 in (0.23 mm)</td>
<td>Box of 5</td>
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</tbody>
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### ROTALINK™ System Catheter and Burr

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Model/Description</th>
<th>Burr Size</th>
<th>Length</th>
<th>Maximum Diameter</th>
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<tbody>
<tr>
<td>H802 22782-001A</td>
<td>ROTABLATOR ROTALINK Advancer (separate from catheter and burr)</td>
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<tr>
<td>H802 22768-002</td>
<td>ROTALINK Exchangeable Burr Catheter</td>
<td>1.25 mm</td>
<td>135 cm</td>
<td>0.58 in (1.47 cm)</td>
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<tr>
<td>H802 22768-003</td>
<td>ROTALINK Exchangeable Burr Catheter</td>
<td>1.50 mm</td>
<td>135 cm</td>
<td>0.58 in (1.47 cm)</td>
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<tr>
<td>H802 22768-004</td>
<td>ROTALINK Exchangeable Burr Catheter</td>
<td>1.75 mm</td>
<td>135 cm</td>
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<tr>
<td>H802 22768-005</td>
<td>ROTALINK Exchangeable Burr Catheter</td>
<td>2.00 mm</td>
<td>135 cm</td>
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<tr>
<td>H802 22768-015</td>
<td>ROTALINK Exchangeable Burr Catheter</td>
<td>2.15 mm</td>
<td>135 cm</td>
<td>0.58 in (1.47 cm)</td>
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<td>ROTALINK Exchangeable Burr Catheter</td>
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<td>135 cm</td>
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<tr>
<td>H802 22768-016</td>
<td>ROTALINK Exchangeable Burr Catheter</td>
<td>2.38 mm</td>
<td>135 cm</td>
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<td>H802 22768-007</td>
<td>ROTALINK Exchangeable Burr Catheter</td>
<td>2.50 mm</td>
<td>135 cm</td>
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<tr>
<td>Order Number</td>
<td>Model/Description</td>
<td>Burr Size</td>
<td>Length</td>
<td>Maximum Diameter</td>
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<tr>
<td>--------------</td>
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</tr>
<tr>
<td>H749 23631-002 0</td>
<td>ROTALINK Pre-connected Exchangeable Burr Catheter and Advancing Device</td>
<td>1.25 mm</td>
<td>135 cm</td>
<td>0.58 in (1.47 cm)</td>
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<tr>
<td>H749 23631-003 0</td>
<td>ROTALINK Pre-connected Exchangeable Burr Catheter and Advancing Device</td>
<td>1.50 mm</td>
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<td>135 cm</td>
<td>0.58 in (1.47 cm)</td>
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<td>0.58 in (1.47 cm)</td>
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<td>H749 23631-016 0</td>
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<td>135 cm</td>
<td>0.58 in (1.47 cm)</td>
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<tr>
<td>H749 23631-007 0</td>
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<td>2.50 mm</td>
<td>135 cm</td>
<td>0.58 in (1.47 cm)</td>
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**Console**

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<tr>
<td>H802 21600-003 1</td>
<td>Replacement Braided Air Supply Hose (20 feet)</td>
<td>Single</td>
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<tr>
<td>H802 22436-002 1</td>
<td>Dynaglide™ Foot Pedal</td>
<td>Single</td>
</tr>
<tr>
<td>H802 22196-003 2</td>
<td>WireClip™ Torquer</td>
<td>Box of 5</td>
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</tbody>
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Note: Boston Scientific is not responsible for the correct use of codes on submitted claims; this information does not constitute reimbursement or legal advice.